UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

LOUISIANA HEALTH SERVICE & INDEMNITY COMPANY D/B/A BLUE CROSS AND BLUE SHIELD OF LOUISIANA, HMO LOUISIANA, INC., and DAVID MITCHELL, individually and on behalf of all others similarly situated, Plaintiffs, v. CELGENE CORPORATION, BRISTOL MYERS SQUIBB COMPANY, ANTHONY INSOGNA, and JEROME ZELDIS, Defendants.	Civil Action No. 1:23-cv-07871 **REDACTED**

OPPOSITION TO DEFENDANTS' MOTIONS TO DISMISS
[ECF NOS. 108, 117, 120]

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I. INTRODUCTION

BMS[1] sells Pomalyst, a multi-billion dollar a year drug used in the treatment of multiple myeloma. Beginning in 2017, at least seven drug manufacturers filed ANDAs to sell pomalidomide, bringing the promise of more affordable generic versions of the drug. On October 30, 2020, the FDA granted final approval to two of those ANDA filers, clearing the way for immediate generic entry—and substantial profits to those two generics. But neither generic launched. Instead, they, and all other generic Pomalyst ANDA filers, agreed to delay generic entry for more than five years, until the first quarter of 2026 (coinciding with the end of a monopoly profit share agreement on the related drug Revlimid). BMS obtained this lucrative delay period not through innovation or superior acumen, but through a decades-long monopolization scheme, involving fraud on the patent office, sham litigation, and unlawful reverse payments, that has caused, and will continue to cause, significant harm to patients and other drug purchasers.

Celgene defrauded the patent office to obtain pomalidomide patents. In the 1990s and early 2000s, clinical researchers at Boston Children's Hospital, Dana-Farber Cancer Institute, and other research centers studied and published extensively on the use of pomalidomide (and its analogs lenalidomide and thalidomide) to treat cancer and other conditions. If Celgene wanted to claim for itself a monopoly on this well-known drug, it would need patents. And to get those patents, it would need to find a way around earlier published pomalidomide studies, journal articles, and patents. Aided by its Chief Medical Officer Jerome Zeldis and its patent counsel Anthony Insogna, Celgene falsified and omitted material information about this significant body of earlier work in its submissions to patent office examiners. Beginning in 2012, the patent office rewarded Celgene for its duplicity with a handful of incorrectly issued Pomalyst patents.

[1] Bristol-Myers Squibb Company acquired Celgene Corporation in 2019. As used herein, "BMS" refers to BMS and Celgene collectively. We refer to "Celgene" when addressing pre- November 2019 conduct.

Celgene then asserted those patents in sham patent litigation. In 2017, Celgene began asserting its fraudulently obtained pomalidomide patents in infringement litigation it knew it could not win, but pursued because it would block generic competition for Pomalyst (at least for a time). Although meritless, the filing of the litigation triggered an automatic thirty month stay (subsequently extended), during which the generics could not obtain final approval (and therefore could not launch). That ended in 2020 when the stay expired, and FDA granted final approval to two ANDA filers. Faced with imminent generic launch, BMS pivoted to the next phase of the unlawful monopolization scheme: pay-for-delay agreements.

The monopolization scheme culminated in pay-for-delay settlements, prolonging the harm to patients and other drug purchasers. When the clock ran out on the defendants' patent litigation stall tactic, BMS bribed the generics to stay off the market for more than five years by: (a) delaying generic Pomalyst entry to coincide with the end of the Revlimid monopoly profit share period, maximizing the generics' monopoly profits on both drugs; (b) granting the settling generics [redacted] that deterred further patent challenges; and (c) removing the then-existing risk that first filers had lost their lucrative exclusivity period.

Because of the unlawful monopolization scheme, patients and other drug purchasers have paid, and will continue to pay, overcharges on Pomalyst, a thirty-year-old drug for which BMS currently charges approximately $200,000 per patient per year. The complaint adequately alleges an unlawful monopolization scheme, and the claims should be sustained.

II. FACTS

A. Celgene obtained patents through fraud to block generic competition.

In the 1990s thalidomide proved effective in treating a condition associated with leprosy, renewing interest in thalidomide and its analogs. Beginning in 1993 Dr. Robert D'Amato, a doctor at Boston Children's Hospital, filed several patent applications disclosing thalidomide and its-analogs,

including pomalidomide, to treat diseases mediated by the growth of unwanted blood vessels associated with cancer and other conditions.[2] Children's Hospital partnered with EntreMed, to develop these analogs into drugs.[3] In 1997, Celgene obtained the 5,635,517 patent, which claims the compound lenalidomide. The '517 also claimed methods of using pomalidomide to reduce TNFα and taught that reducing TNFα is "a valuable therapeutic strategy for the treatment of . . . cancer. . . ."[4] In July 2001, Davies and others published an article teaching pomalidomide to treat multiple myeloma and relapsed/refractory disease.[5] In December 2001, D'Amato and others published an article that taught pomalidomide for the treatment of multiple myeloma.[6] D'Amato referred to pomalidomide as "3-aminothalidomide", where others used "4-aminothalidomide."[7]

By 2002, D'Amato, Children's Hospital, and EntreMed had a portfolio of intellectual property and EntreMed planned to seek FDA-approval for a pomalidomide drug.[8] Celgene "embarked on an intentional campaign to harm EntreMed."[9] Celgene interfered in the prosecution of D'Amato's patent applications and sued the U.S. Patent and Trademark Office (PTO) to stop it from issuing of pomalidomide patents to D'Amato. In November 2002, EntreMed sued Celgene for antitrust violations. Faced with this lawsuit, Celgene changed course, it exclusively licensed from D'Amato 75+ patents and patent applications that claim, e.g., methods of using pomalidomide (using the unusual 3-aminothalidomide nomenclature) and other thalidomide analogs.[10] All of this

[2] Amended Compl. & Demand for Jury Trial, ECF No. 71, ¶¶89–95 ("Compl.").

[3] Compl., ¶141.

[4] Compl., ¶¶103, 168.

[5] Compl, ¶¶124–140.

[6] Compl., ¶¶131–132.

[7] The difference is due to a chemistry naming convention; there is no question about what compound is referenced.

[8] Compl., ¶141.

[9] Compl., ¶142, quoting *EntreMed, Inc. v. Celgene*, 02-3787 (D. Md.), Compl., ¶13 (filed Nov. 21, 2002).

[10] Compl., ¶¶143–144, 181.

would become prior art as against Celgene's later filed patent applications. Having obtained control of the D'Amato patent portfolio, Celgene, through Insogna, affirmatively abandoned the patents and applications claiming methods of using pomalidomide. Why? To manage the risk these almost-patents posed to Celgene's ability to obtain later-expiring pomalidomide method of use patents.

Although aware of the prior research teaching pomalidomide to treat multiple myeloma, Celgene, Insogna, and Zeldis began pursuing new patents that claimed methods of using pomalidomide to treat multiple myeloma ('262 prosecution). On August 19, 2008, Celgene applied for what would become the '262.[11] Zeldis was the inventor and Insogna the prosecutor. The patent examiner rejected the application because a combination of references disclosed the cyclical treatment of multiple myeloma with pomalidomide (including the '517 and Davies 2001).[12] To overcome the rejection, Celgene misrepresented and/or omitted the truth about the '517, Davies 2001, and D'Amato 2001. First, on December 23, 2010, Insogna attested,[13] "The PTO admits that the primary reference [the '517] does not teach ACTIMID [i.e.: pomalidomide]".[14] But Celgene, Zeldis, and Insogna knew the '517 did teach pomalidomide – it was, after all, Celgene's most important patent claiming its billion-dollar drug, Revlimid. Second, Celgene, Insogna, and Zeldis repeated the examiner's mistaken belief that Davies (2001) did not teach pomalidomide,[15] by capitalizing on the confusion created by the article's use of "IMiDs" (terminology coined by Celgene). Although the examiner may have been confused, Celgene certainly knew the truth.[16] Third, Celgene, Insogna, and Zeldis misdirected the examiner by arguing

[11] Compl., ¶163.

[12] "While the office action rejected the claims, it did so on the basis that required the combined teaching of the three specific references. The patent examiner was under the misimpression that neither the '517 nor Davies (2001) expressly taught pomalidomide, and that the p'554/'230 did not expressly teach multiple myeloma. Nor did the patent examiner cite other earlier scientific literature or patents showing the treatment of multiple myeloma with pomalidomide itself." Compl., ¶121–123, 166.

[13] December 23, 2010 Amendment to Celgene's 8,198,262 patent application; *see also* 37 CFR §11.18(b)(1).

[14] Compl., ¶174. "ACTIMID" was Celgene's name for pomalidomide.

[15] Celgene stated "the Office admits that [Davies] does not teach [pomalidomide]." Compl., ¶175.

[16] Compl., ¶¶126, 175.

the two patents the examiner cited did not teach the use of pomalidomide to treat cancer, while concealing studies that taught pomalidomide to treat multiple myeloma and other cancers.

Celgene overcame the first rejection by lying. But in August 2011, the examiner again rejected the '262 application. The examiner concluded that "it would have been obvious to one having ordinary skill in the art at the time the invention was made to treat [multiple myeloma] with pomalidomide as suggested by Kyle[,] Davies, Corral and Muller …."[17]

To overcome this rejection, Celgene, along with Zeldis, and Insogna, made three more misrepresentations and/or omissions. First, Celgene stated "there is no suggestion in the cited art that pomalidomide is effective to treat multiple myeloma. . . ."[18] False: D'Amato (2001), Lentzsch (2001), Letnzsch (2002), Schey (April 2002), and Schey (October 2002), all taught this. Second, Celgene suggested that the use of one thalidomide compound over another had not been publicly disclosed.[19] Not true; e.g., during reexamination of the '517 patent, Celgene submitted information to the PTO claiming that pomalidomide was 10,000 times more active than other compounds.[20] Third, Celgene misrepresented that treating cancer with pomalidomide by dosing cyclically was novel. In fact, it was routine.[21] On April 9, 2012—relying on Celgene's, Insogna's, and Zeldis's knowingly false statements and material omissions—the examiner issued the '262 patent.

In 2013, Celgene and Zeldis made false misrepresentations and/or omissions to secure the '3939 and '428 method-of-use patents. On March 1, 2013, one month after launching Pomalyst, Celgene filed two applications seeking to broaden its method-of-use patent protection for pomalidomide. Both

[17] Compl., ¶185. References included Davies (2001), Corral (1999), Muller (1999), and the '554 and '230.

[18] Compl., ¶187, n.72.

[19] Compl., ¶188.

[20] Compl., ¶188.

[21] Compl., ¶192; *see* Kyle (2001), Coleman (2002), and Cohen (1982).

applications addressed, again, the cyclical dosing of pomalidomide.[22] Zeldis was the inventor.

In July 2013, the examiner rejected the applications in light of the '262 patent and extensive earlier studies, articles, and patents (a/k/a prior art).[23] To overcome the rejection, Celgene and Zeldis intentionally misrepresented and/or omitted facts to the examiner. Celgene filed a sworn declaration from its executive Dr. Anjan Thakurta, asserting that treating refractory and/or relapsed multiple myeloma with pomalidomide would have been surprising and unexpected.[24] False: using pomalidomide to treat refractory and/or relapsed multiple myeloma was known,[25] and Celgene had already disclosed that pomalidomide was more potent than other thalidomide analogs. So, it would have been expected that myeloma patients who became resistant to the less potent thalidomide analog (lenalidomide) could be treated with a more potent thalidomide analog (pomalidomide). Celgene also made the same fraudulent misrepresentations and omissions as it had during the '262 prosecution, reinforcing the examiner's mistaken beliefs that: (1) the '517 does not teach pomalidomide; (2) D'Amato (2001) does not teach pomalidomide to treat multiple myeloma; and (3) that Davies (2001) does not teach pomalidomide to treat multiple myeloma and relapse/refractory disease. In reliance on Celgene and Zeldis's misrepresentations and omissions, the examiner issued the '3939 and '428 method of treatment patents in the Spring of 2014.[26]

Celgene and Insogna made false misrepresentations and omissions to secure formulation patents. On May 19, 2010, Celgene and Insogna filed a patent application claiming an oral dosage form of a certain

[22] Compl., ¶¶219–220.

[23] Compl., ¶222. ("The prior art references cited by the examiner included Kyle (2001), Davies (2001), Corral (1999), Muller (1999), and the '554.").

[24] Compl., ¶226. *See also* Compl., ¶¶223-225, 227-228.

[25] *See e.g.*, Davis (2001) (teaching that "IMiDs," including pomalidomide, can act directly on multiple myeloma cells and are useful in relapsed/refractory disease).

[26] Compl., ¶231.

weight comprised of pomalidomide and a pharmaceutically acceptable carrier or excipient.[27] This patent was basically a recipe: combine pomalidomide with a few well-known carriers and excipients (such as mannitol, pregelatinized starch, and sodium stearyl fumarate) in specified ratios. That was the extent of the claimed "invention." Celgene had not invented a "new" recipe, both the instructions and ingredients had been known for years.

The examiner rejected the patent application multiple times for obviousness, including in light of studies, patents, and a textbook.[28] To overcome this rejection, Celgene and Insogna made false statements and omitted material information, including the fact that earlier studies, such as Schey (April 2002), disclosed the acceptable dosage amount for pomalidomide (up to 5mg/day).[29]

After the examiner's second rejection, Celgene and Insogna filed the declaration of a Celgene scientist, Anthony Tutino, stating that many pomalidomide/excipient combinations he tested posed stability issues over time, the claimed invention did not, and that these were "unexpected results" supporting patentability.[30] But thalidomide and its analogs are notoriously unstable; they degrade in the presence of water, a fact that had been well known and documented in the scientific community since at least 1965.[31] And it would have been routine to address this stability issue in the formulation process. There was nothing "unexpected," but the examiner—deceived by the fraudulent declaration and the concealment of the prior art—allowed the '427 formulation patent to issue.

Celgene made false misrepresentations and omissions to secure the '467 and '5939 formulation patents. Next, Celgene sought patent protection for more formulations. On December 23, 2015, Celgene

[27] Compl., ¶207.

[28] Compl., ¶208.

[29] Compl., ¶¶204, 210.

[30] Compl., ¶213.

[31] Compl., ¶214; *see also id.* at n 76, citing H. Schumacher, R. L. Smith, and R.T. Williams, *The Metabolism of Thalidomide: The Spontaneous Hydrolysis of Thalidomide in Solutions*, Brit. J. Pharmacol. (1965), 25, 324–337 ("we shall describe the conditions for the spontaneous hydrolysis of thalidomide in aqueous solution . . . .").

applied for a patent claiming formulations in terms of relative weight. The patent examiner repeatedly rejected the claims.[32] To overcome the rejection, Celgene amended its claims requiring that the starch to mannitol ratio be from 1:1 to 1:1.5 (only) and submitted another fraudulent declaration by Tutino, again touting "surprising and unexpected" stability results.[33] Celgene's deception worked; on March 15, 2018, the examiner allowed the '467 formulation patent to issue.[34]

On May 10, 2018, Celgene filed another application claiming broader ranges of relative weight in two of its claims.[35] The examiner rejected the application four times. Celgene resubmitted the false Tutino Declarations claiming "unexpected results." This time, the examiner was not buying it, but allowed the patent to issue subject to a terminal disclaimer, which required the patent term to end when the '467 patent expired.[36] Celgene got broader ranges, but no more time.

After generics filed pomalidomide ANDAs, Celgene obtained three crystal form patents. On December 20, 2017, Celgene filed three patent applications, months after Celgene sued Pomalyst ANDA filers. On October 9, 2018, the PTO issued the 10,093,647, 10,093,648, and 10,093,649 patents. Each has a single independent claim, for a dihydrate, hemihydrate, or monohydrate form,[37] identified by an x-ray powder diffraction ("XRPD") pattern (basically a unique thumbprint for a crystalline form).

Celgene, Zeldis and Insogna obtained nine pomalidomide patents. Celgene's pomalidomide patents were unenforceable, invalid and/or would not be infringed by competitor products:

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[32] Compl., ¶¶234–235. ("Zeldis teaches a limited list of fillers… a limited list of disintegrants… a limited list of lubricants… [and] a person of ordinary skill in the art would have arrived at the claimed invention through routine examination and it would have been obvious to have formed a solid dosage form from any possible combination of excipients disclosed by Zeldis.").

[33] Compl., ¶241.

[34] Compl., ¶242.

[35] Compl., ¶267.

[36] Compl., ¶¶270–271.

[37] A hydrate is a compound containing water. The prefix indicates the number of water molecules to each molecule of water. For example, a dihydrate contains two molecules of water for each molecule of the compound.

Category[38]	Patents
Method of treatment/use patents	'262, '428, '3939
Formulation/oral dosage patents	'427,[39] '467, '5939
Crystal form patents	'647, '648, '649

B. Though unenforceable and invalid, Celgene (and later BMS) asserted the pomalidomide patents to block generic competition.

Celgene launched Pomalyst in 2013. In February 2013, Celgene launched Pomalyst. Generics could not file Pomalyst ANDAs until four years later, in February 2017.[40]

Meanwhile, Celgene began settling patent litigation involving thalidomide-analog Revlimid. In December 2015, Celgene began settling Revlimid litigation, first with Natco, then with Aurobindo, Apotex, Mylan, Hetero, Alvogen/Lotus, and Dr. Reddy's[41] (collectively, the "limited-volume Revlimid licensees"). In March 2022, Natco began selling mid-single digit percentages of generic Revlimid; beginning in September 2022 other limited-volume Revlimid licensees could begin selling small amounts too. The generics' allowed percentage of Revlimid sales remains constrained until the first quarter of 2026, when the Revlimid volume restrictions end. Because the generics are selling small, fixed quantity percentages of the Revlimid market, there is no incentive to compete on price.[42]

With its Revlimid revenue stream secured for another decade, Celgene (and BMS) took steps to maximize monopoly profits on Pomalyst. On February 8, 2017, Natco/Breckenridge, Teva, Aurobindo, Apotex,

[38] *See, e.g.* Compl., ¶318.

[39] Celgene later withdrew its infringement claims against the generics as to '427 before most settlements occurred. Compl., ¶256.

[40] *See* Compl., ¶26 & n. 10; *see also* 21 U.S.C. § 355(j)(5)(F)(ii); 21 C.F.R. § 314.108(b)(2).

[41] Hetero's wholly-owned subsidiary, Camber, began selling limited quantities of generic Revlimid in June 2023.

[42] Compl., ¶¶325, 327, 349.

Mylan, and Hetero (and later Alvogen/Synthon and Dr. Reddy's[43]) filed pomalidomide ANDAs.[44] In May 2017, Celgene began suing each generic.[45] The patent litigation triggered an automatic 30-month stay during which the FDA could not grant final approval to any generic product. Celgene filed and maintained the litigation knowing it could not win, because: its pomalidomide method of use patents were fraudulent and invalid as obvious due to earlier research; the formulation patents were fraudulent and easily designed around to avoid infringement; and, the polymorph patents, cannot be both novel over what came before (i.e., valid) and simultaneously infringed by what came before.[46]

The generic defendants developed a strong record of invalidity and non-infringement, and obtained a favorable June 16, 2020 claims construction decision. Judge Salas ruled that the method of treatment patents did not claim efficacy, which BMS had conceded (for tactical reasons) would mean the patents were invalid; they posed no impediment to generic entry. Only two formulation patents[47] and the crystal form patents remained in dispute.

On October 30, 2020, FDA granted final approval to Natco/Breckenridge and Aurobindo, clearing the way for an immediate generic launch that would have taken a majority of brand sales and earned the two generic companies roughly $300 million in the first six months alone.[48]

Instead of launching, Natco and Aurobindo settled. In Fall 2020, in exchange for payments, Natco and Aurobindo agreed to wait more than five years to launch. Given the clear weakness of Celgene's pomalidomide patents, an economically rational generic company would not forgo

[43] In 2018 and 2019, Synthon/Alvogen and Dr. Reddy's filed ANDAs for Pomalyst. Compl., n. 86.

[44] Compl., ¶¶246, 247. Par also filed a Pomalyst ANDA with paragraph IV certification, but shortly after Celgene filed for patent infringement, Par converted its paragraph IV to a paragraph III and stipulated to dismissal.

[45] Compl., ¶250.

[46] Compl., ¶283.

[47] Compl., ¶¶ 279–281, 298–302. Celgene abandoned its claims for one of the three formulation patents for undisclosed reasons.

[48] Compl., ¶¶338–341.

hundreds of millions of dollars in immediate profits, instead launching in a genericized market where they will make less than $20 million, without getting something in return.[49] Though the size of the payment will be determined by discovery, it exceeds $300 million and took three forms.

Put differently, generics did not settle because the patents were strong; again, the complaint alleges they are fraudulent and weak. Instead, the generics settled (on anticompetitive terms) because BMS promised them more than they could get if they won the patent disputes: protection of profits from an unlawfully allocated Revlimid market, protection against the risk of forfeiting the 180-day exclusivity, and supracompetitive profits from assurance of mutually timed generic entry.

First, BMS paid the Pomalyst ANDA filers to delay by sharing BMS's monopoly profits on Revlimid. Other than Par (which withdrew its paragraph IV letter almost immediately), all Pomalyst ANDA filers (or their commercialization partner) had a volume-limited license for generic Revlimid:[50]

	Par	Natco	Teva	Alvogen	Dr. Reddy's	Apotex	Aurobindo	Mylan	Hetero
Pomalyst ANDA	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Revlimid Limited Volume License?	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

The Revlimid profit share began in March 2022 and will not end until Q1 2026. The same generics agreed to delay entry on generic Pomalyst until then too. Pomalyst ANDA filers maximized their monopoly profits on both Revlimid and Pomalyst through restraints on competition.

Second, BMS paid generics by granting the first ANDA filers [redacted] The Pomalyst agreements with Natco/Breckenridge, Aurobindo, and Teva [redacted]

[redacted]

[49] Compl., ¶344.

[50] Compl., ¶¶325, 327, 349, 360. Natco partnered with Allergen and Teva on Revlimid and with Breckenridge on Pomalyst. Alvogen partnered with Lotus on Revlimid and with Synthon on Pomalyst; and it appears that Hetero's wholly-owned subsidiary, Camber, was party to the Revlimid limited-volume license. Source: publicly available sales data.

[redacted][51]

Third, BMS granted the generics [redacted][52] When they settled, it was uncertain whether the FDA would deem that the first filers' 180 day exclusivity period had indeed been forfeited.[53] [redacted]

III. LEGAL STANDARD

In ruling on a motion to dismiss for failure to state a claim, the court must liberally construe all claims, accept the factual allegations in the complaint as true, and draw all reasonable inferences in favor of the nonmoving party.[54] To survive a motion to dismiss, "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'"[55] "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged."[56] "'[T]here is no

[51] Compl., ¶¶326–327.

[52] Compl., ¶¶290–292.

[53] Compl., n. 97.

[54] *In re Novartis & Par Antitrust Litig.*, No. 18 Civ. 12293, 2019 WL 3841711, at *3 (S.D.N.Y. Aug. 15, 2019) (citing *Gregory v. Daly*, 243 F.3d 687, 691 (2d Cir. 2001)). *See also Sergeants Benevolent Ass'n Health & Welfare Fund v. Actavis, PLC,* No. 15-cv-6549 (CM), 2018 WL 7197233, at *11 (S.D.N.Y. Dec. 26, 2018) ("*Namenda II*") (addressing motion to dismiss re state law claims) (citing *Cargo Partner AG v. Albatrans, Inc.*, 352 F.3d 41, 44 (2d Cir. 2003)).

[55] *Ashcroft v. Iqbal*, 556 U.S. 662, 678, 129 S. Ct. 1937, 173 L. Ed. 2d 868 (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570, 127 S. Ct. 1955, 167 L. Ed. 2d 929 (2007)).

[56] *Id.* at 678.

heightened pleading standard in antitrust cases.'"[57] At the pleading stage, the purchasers "need only raise a reasonable expectation" that discovery will reveal evidence of an antitrust violation.[58]

IV. ARGUMENT

A. The complaint adequately alleges BMS and Celgene's anticompetitive scheme violates Sherman Act § 2 and analogous state laws.[59]

Under § 2 of the Sherman Act, it is unlawful to "monopolize, or attempt to monopolize . . . any part of the trade or commerce among the several States."[60] To allege a monopolization claim, a plaintiff need only allege that (i) the defendant had monopoly power, (ii) committed an antitrust violation, (iii) causing the plaintiffs antitrust injuries.[61] In this case, the defendants do not contest the monopoly power allegations or that the scheme caused injury and overcharges through generic delay. Instead, the defendants focus their attack on the purchasers' allegations of antitrust violations.

The complaint alleges a scheme comprised of (i) fraudulently obtaining patents, (ii) enforcing those patents in sham litigation, and (iii) settling on anticompetitive terms, which delayed generic entry. The Supreme Court and the Second Circuit hold "the character and effect of a conspiracy are not to be judged by dismembering it and viewing its separate parts, but only by looking at it as a

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[57] *Wacker v. JP Morgan Chase & Co.*, No. 16-2482-CV, 2017 WL 442366, at *29 (2d Cir. Feb. 1, 2017) (quoting *Concord Assocs., L.P. v. Entm't Props. Trust*, 817 F.3d 46, 52 (2d Cir. 2016)); *see also In re Lipitor Antitrust Litig.*, 868 F.3d 231, 254 (3d Cir. 2017) (holding it was error for district court to apply heightened pleading standard to reverse payment allegations); *FTC v. Abbvie,* 976 F.3d 327, 354 (3d Cir. 2020) (noting the court had already rejected the need for a "reliable monetary estimate" or a heightened pleading standard in *Lipitor* and *King Drug*, holding it inconsistent with *Twombly*, *Iqbal, and Actavis.*); *In re Loestrin 24 Fe Antitrust Litig.*, 814 F.3d 538, 552 (1st Cir. 2016) ("Consistent with *Twombly*, which declined to 'require heightened fact pleading of specifics,' *Twombly*, 550 U.S. at 570, 127 S. Ct. 1955, we do not require that the plaintiffs provide precise figures and calculations at the pleading stage. . . .").

[58] *Wacker,* 2017 WL 442366, *30 (quoting *Mayor & City Council of Balt. v. Citigroup Inc.*, 709 F.3d 129, 135 (2d Cir. 2013)).

[59] BMS' motion challenges the adequacy of the state law claims only insofar as those allegations are insufficient under federal law analysis. Having raised no other basis to dismiss the state law claims, such arguments are waived. *See* BMS Mem. at n.3.

[60] 15 U.S.C. § 2.

[61] *United Food & Commercial Workers Local 1776 & Participating Employers Health & Welfare Fund v. Takeda Pharm Co. Ltd.,* 11 F.4th 118, 137–138 (2d Cir. 2021) ("*Actos*"). *See also In re Namenda Direct Purchaser Antitrust Litig.*, 331 F. Supp. 3d 152, 177 (S.D.N.Y. 2018) (quoting *In re Visa Check/Master Money Antitrust Litig.*,280 F.3d 124, 136 (2d Cir. 2001)).

whole."[62] Courts look holistically at antitrust schemes; schemes to delay generic entry are canonical monopolization claims; courts regularly hold them sufficiently plead.[63]

BMS's invitation to atomize invites error. The defendants seek to improperly slice the purchasers Section 2 claim into 3 separate and independent causes of action (*e.g.*, "reverse payment claim," "*Walker Process* fraud claims"). Again, "courts must look to the monopolist's conduct taken as a whole rather than considering each aspect in isolation."[64]

B. The complaint adequately alleges exceptions to *Noerr-Pennington* limited immunity.

The Supreme Court's *Noerr-Pennington* doctrine provides limited antitrust immunity to petition the government for redress of grievances.[65] The scope depends on "the source, context, and

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[62] *Cont'l Ore Co. v. Union Carbide & Carbon Corp.*, 370 U.S. 690, 699 (1962); *In re Elec. Books Antitrust Litig.*, 859 F. Supp. 2d 671, 689 (S.D.N.Y. 2012) (quoting *Cont'l Ore Co.*, 370 U.S. at 699). *See also In re Suboxone (Buprenorphine Hydrochloride and Naloxone) Antitrust Litig.*, 622 F. Supp. 3d 22, 60 (E.D. Pa. 2022) ("Alleged antitrust conduct must be scrutinized as a whole…") (citing *Cont'l Ore*). *SD3, LLC v. Black & Decker (U.S.) Inc.*, 801 F.3d 412, 425 (4th Cir. 2015) ("Actions that might seem otherwise neutral in isolation can take on a different shape when considered in conjunction with other surrounding circumstances."); *Robertson v. Sea Pines Real Est. Cos. Inc.*, 679 F.3d 278, 291 (4th Cir. 2012) (sustaining antitrust claim based on alleged acts that "cumulatively enabled the defendants to exclude lower-cost brokerages from effectively competing in the local real estate markets").

[63] *E.g., In re Restasis (Cyclosporine Ophthalmic Emulsion) Antitrust Litig.*, 355 F. Supp. 3d 145, 150 (E.D.N.Y. 2018) (holding EPP plaintiffs sufficiently plead a monopolization scheme based on a "number of improper actions" to delay generic Restasis, including: (1) filing sham citizen petitions; (2) defrauding the patent office; (3) file sham litigation.). *FTC v. Vyera Pharms., LLC,* 479 F. Supp. 3d 31, 39 (S.D.N.Y. 2020) (holding the FTC sufficiently alleged a monopolization claim where brand drug company "implemented a comprehensive scheme to block lower-cost generic drug competition" through distribution agreements, exclusive supply contracts, and data-blocking agreements that were considered as a whole); *United States v. Apple, Inc.*, 791 F.3d 290, 319 (2d Cir. 2015) (Finding plaintiffs sufficiently plead a monopolization scheme by combining the "unmistakable purpose" of exclusionary contracts, subsequent parallel comment, and circumstantial evidence); *In re DDAVP Direct Purchaser Antitrust Litig.,* 585 F.3d 677, 683 (2d Cir. 2009) (holding plaintiffs' *Walker Process* and sham litigation generic delay claims sufficiently plead a monopolization claim) *Restasis*, 355 F. Supp. 3d at 150 (holding EPP plaintiffs sufficiently plead a generic suppression monopolization scheme including fraud on the USPTO and baseless, sham litigation). *See also In re Loestrin 24 Fe Antitrust Litig.*, 261 F. Supp. 3d 307, 357 (D.R.I. 2017) (finding plaintiffs sufficiently plead a monopolization including fraud on the USPTO).

[64] *LePage's Inc. v. 3M*, 324 F.3d 141, 162 (3d Cir. 2003) (citing *Cont'l Ore Co. v. Union Carbide & Carbon Corp.*, 370 U.S. 690, 698-99 (1962)); *see also In re Nat'l Football League's Sunday Ticket Antitrust Litig.*, 933 F.3d 1136, 1152 (9th Cir. 2019) (the conduct at issue is "not to be judged by dismembering it and viewing its separate parts, but only by looking at it as a whole.") (quoting *Cont'l Ore Co. v. Union Carbide & Carbon Corp.*, 370 U.S. 690, 698-99 (1962)); *SD3, LLC*, 801 F.3d at 425 ("Actions that might seem otherwise neutral in isolation can take on a different shape when considered in conjunction with other surrounding circumstances.").

LePage's Inc., 324 F.3d at 162 (citing *Cont'l Ore Co. v. Union Carbide & Carbon Corp.*, 370 U.S. 690, 698–99 (1962)).

[65] *See E.R.R. Presidents Conference*, 365 U.S. at 127; *United Mine Workers of Am. v. Pennington*, 381 U.S. 657 (1965).

nature of the anticompetitive restraint at issue."[66] It does not offend the First Amendment to hold one who misuses and abuses governmental processes accountable for its anticompetitive actions.[67] *Noerr*'s limited protections disappear when a petitioner (a) pursues sham litigation *or* (b) defrauds the PTO.[68] This is fact-intensive inquiry, not appropriate for resolution on a motion to dismiss.[69]

1. The complaint adequately alleges *Walker Process* theories.

As the Supreme Court recognized in *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, enforcing a patent obtained by fraud can violate § 2 of the Sherman Act.[70] Enforcing a patent obtained by fraud warrants no First Amendment protection.[71] To prove *Walker Process* fraud, a plaintiff must show the defendant (1) knowingly and willfully made a false representation or deliberate omission of fact which was material; (2) that it was done with an intent to deceive the examiner; (3) that the examiner relied upon the misrepresentation or omission when issuing the

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[66] *Allied Tube & Conduit Corp. v. Indian Head, Inc.*, 486 U.S. 492, 499 (1988).

[67] *See e.g.*, *Eastern R.R. President's Conf. v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 144 (1961)*; United Mine Workers of America v. Pennington,* 381 U.S. 657, 669-672 (1965); *DDAVP*, 585 F.3d at 684 ("while conduct in obtaining and enforcing a patent is generally protected from antitrust liability by the First Amendment, a patentee loses this immunity and can incur antitrust liability for enforcing a patent if the patent was obtained by fraud on the PTO.").

[68] *See infra,* Sections IV(B)(1)–(2).

[69] *See e.g., Actava TV Inc. v. Joint Stock Co. "Channel One Russia Worldwide",* No. 18-cv-06626 (ALC), 2024 WL 1156614, at *10 (S.D.N.Y. Mar. 18, 2024) (in summary judgment posture, noting that "whether the sham exception ought to apply should proceed to a jury"); *Truck-Lite Co. v. Grote Indus., Inc.*, No. 18-CV-599, 2021 WL 8322467, at *12 (W.D.N.Y. Sept. 17, 2021) ("Determinations of whether a party's conduct is a genuine attempt to avail itself of the judicial process or is merely a sham is a question of fact that is inappropriate for a motion to dismiss.").

[70] 382 U.S. 172, 174 (1965) ("We have concluded that the enforcement of a patent procured by fraud on the Patent Office may be violative of section 2 of the Sherman Act provided the other elements necessary to a section 2 case are present."); *see also Unitherm Food Sys., Inc. v. Swift-Eckrich, Inc.*, 375 F.3d 1341, 1347–1358 (Fed. Cir. 2004) ("Strictly speaking, a *Walker Process* claim is premised upon 'the enforcement of a patent procured by fraud on the Patent Office.'") (quoting *Walker Process*, 382 U.S. at 174), *rev'd on other grounds*, 546 U.S. 394 (2006).

[71] *See, e.g.*, *Eastern R.R. President's Conf. v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 144 (1961); *see also Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 56 (1993) ("*PRE*"); *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1068 (Fed. Cir. 1998) (Antitrust liability attaches if "(1) [] the asserted patent was obtained through knowing and willful fraud . . . , *or* (2) [] the infringement suit was 'a mere sham to cover what is actually nothing more than an attempt to interfere directly with the business relationships of a competitor.'") (emphasis added); *see also In re Buspirone Patent Litig.*, 185 F. Supp. 2d 363, 369 (S.D.N.Y. 2002) ("[T]he *Walker Process* exception co-exists with the sham litigation exception under *PRE* and . . . either exception will strip a patent holder of *Noerr-Pennington* immunity.") (citations omitted).

patent; and that (4) but for the misrepresentation or omission the patent would not have issued. [72] To satisfy Rule 9(b), plaintiffs must "identif[y] the specific who, what, when, where, and how of the material misrepresentation or omission committed before the PTO."[73]

False representations can be failures to disclose material information, submissions of false material information, or affirmative misrepresentations of material facts.[74] Omissions can be material misrepresentations "sufficient to support a finding of *Walker Process* fraud" where the complaint alleges intent.[75] A plaintiff need not be clairvoyant: "intent, knowledge, and other conditions of a person's mind may be alleged generally."[76] The Second Circuit instructs leniency on such issues on a motion to dismiss, as they are more appropriately resolved by a trier of fact.[77] "The characterization of a state of mind, after all, does not lend itself to detailed pleading."[78]

a. The complaint details facts supporting *Walker Process* fraud as part of the defendants' monopolization scheme.

[72] *DDAVP*, 585 F.3d at 685.

[73] *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1328 (Fed. Cir. 2009).

[74] *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1178 (Fed. Cir. 1995).

[75] *DDAVP*, 585 F.3d at 692 (citing *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1070 (Fed. Cir. 1998)) ("A fraudulent omission can be just as reprehensible as a fraudulent misrepresentation."). *See id.,* at 693 (Omissions can be considered sufficient to establish a *Walker Process* fraud violation if the plaintiff can show "intent separable from the simple fact of the omission.") (quoting *Dippin' Dots, Inc. v. Mosey*, 476 F.3d. 1337, 1347 (Fed. Cir. 2007)).

[76] Fed. R. Civ. P. 9(b).

[77] *DDAVP*, 585 F.3d at 693 (deciding this issue on summary judgment but clarifying its reasoning applies at the motion to dismiss stage too).

[78] *United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 228 (1st Cir. 2004), *abrogated on other grounds by Allison Engine Co., Inc. v. U.S. ex rel. Sanders*, 553 U.S. 662 (2008); *see also In re Effexor XR Antitrust Litig.*, No. 11-5479 (PGS)(LHG), 2014 WL 4988410, at *26 (D.N.J. Oct. 6, 2014), *rev'd and remanded sub nom. Lipitor*, 868 F.3d at 249 (reversed on other grounds) ("[g]enerally, lack of proof of intent within the four corners of the pleading is not a reason to dismiss a complaint."); *Loestrin*, 261 F. Supp. 3d at 341 ("[C]ourts have cautioned that '[s]cienter or intent to defraud is usually an issue of fact that should not typically be resolved on a pretrial motion.'" (quoting *Effexo*r, 2014 WL 4988410, at *26)).

The complaint alleges Celgene committed repeated fraud on patent examiners to obtain late expiring patents, including Pomalyst method of treatment patents (the '262, '3939, '428) and formulation patents (the '427, '467, and '5939), as part the defendants' monopolization scheme.[79]

With respect to the pomalidomide multiple myeloma patents, Celgene and its agents Zeldis and Insogna made clear cut false statements and omissions of material fact, without which the patents would not have issued, including with respect to: (1) the '517 (falsely stating it does not teach pomalidomide); (2) Davies (2001) (misleading the examiner by suggesting it did not teach pomalidomide to treat multiple myeloma and relapsed/refractory disease); (3) D'Amato (2001) (omitting to disclose it taught pomalidomide to treat multiple myeloma); (4) whether earlier research taught pomalidomide to treat multiple myeloma; (5) whether the prior art taught cyclical dosing; (6) whether it was surprising that the more potent analog pomalidomide could be used to treat myeloma that had become to resistant to the less potent analog lenalidomide; and (7) whether using pomalidomide to treat refractory and/or relapsed multiple myeloma was surprising. The examiner relied on the defendants' false statements and omissions when issuing the method patents.

Celgene also lied and omitted material information to obtain the pomalidomide formulation patents by: (1) submitting two false declarations (both by Tutino) misrepresenting to the examiner that Celgene unexpectedly solved for stability issues;[80] and (2) omitting that Schey (April 2002) taught dosage for pomalidomide. The examiner relied on the false declarations and material omissions in issuing the pomalidomide formulation patents.[81]

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[79] BMS argues that Celgene's conduct with respect to the D'Amato patent portfolio does not constitute fraud. BMS Mem. 27–29. The *Walker Process* fraud allegations do not rest on those allegations; they are, though, part of the scheme.

[80] Compl., ¶¶213–214, 241, 243.

[81] In 2018 and 2020, Celgene obtain two more formulation patents, the 9,993,467 and 10,555,939 (respectively), which are in the same family as, and contain claims similar to, the '427.

For each alleged misrepresentation and omission, the complaint "identif[ies] the specific who, what, when, where, and how of the material misrepresentation or omission committed before the PTO."[82] The *Walker Process* fraud theories should be sustained.

b. BMS mischaracterizes the *Walker Process* allegations.

BMS argues: (1) Celgene and its agents made no misrepresentation or omission to the patent office, but even if they did (2) none of the misrepresentations and omissions were material or (3) if they were material, they were duplicative. The defendants are wrong.

The complaint details the material misrepresentations and omissions made to the patent examiner to obtain the patents. The complaint alleges with specificity: the ten false statements and omissions Celgene and its agents made to the examiner to overcome his rejections and obtain the incorrectly issued method of treatment and formulation patents; why they were knowingly false; that the misrepresentations and omissions were material; and facts suggesting the examiner relied on those lies and omissions when issuing the patents. To the extent the defendants dispute these allegations, they are questions of fact for the jury, not suitable for resolution at the pleadings stage. The purchasers' Walker Process fraud theories should be sustained.[83]

The purchasers adequately allege that BMS' misrepresentations and omissions were material. In *Eisai Co., Ltd. v. Dr. Reddy's Laboratories, Ltd.*, this Court held that "information is material to the prosecution of a patent where 'there is a substantial likelihood that a reasonable examiner would have considered the information important in deciding whether to allow the application to issue as a patent.'"[84] The purchasers adequately allege facts to suggest that a reasonable examiner would have considered the false and omitted information important when deciding whether to issue the patents.

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[82] *Exergen Corp.*, 575 F.3d at 1327.

[83] *See* Facts (Section X) and the preceding section (Section B.1.2).

[84] *Eisai Co., Ltd. v. Dr. Reddy's Labs., Ltd.*, No. 03 Civ. 9053 (GEL), 2007 WL 1437834, at *20 (S.D.N.Y. May 11, 2007) (internal citations omitted).

To refute these well-pled allegations, BMS offers alternative (and unconvincing) re-interpretations of the facts. For example, in response to the allegations that Celgene lied about its own patent, the '517, the defendants argue that the examiner was "free to reach his own conclusions" regarding the '517 patent and that Celgene merely offered an "interpretation of what the ['517 reference] disclose[d]."[85] Even if the argument were credible (it is not), these are disputes of fact not appropriate for resolution on a motion to dismiss. The complaint alleges materiality.

The defendants' misrepresentations and omissions are assessed as a whole. BMS argues that, even if Celgene and its agents made misrepresentations and omissions during the patent prosecutions, it doesn't matter because the falsified and omitted information was otherwise taught in (unspecified) "cumulative" references known to the examiner. BMS fails to support this fact intensive argument by, for example, identifying *what* prior art references disclosed the information Celgene and its agents lied about and hid. What BMS's argument boils down to is this: it's ok that we lied to the examiner because he knew we were lying. The argument has no support in fact or law.[86]

Second, circuit court precedent teaches that courts must look at the fraud collectively. In *Luv n' Care, Ltd.* the Federal Circuit held that "[w]hen a person having a duty of candor and good faith has engaged in serial misconduct during the prosecution of the same or related patents, it is not enough for a court to consider each individual act of misconduct without also considering the collective whole."[87] Celgene and its agents' lies and omissions allowed them to move forward in the patent prosecution and overcome earlier rejections. The fact that Celgene, Insogna, and Zeldis were

[85] BMS Mem. of Law in Supp. of Mot. to Dismiss, ECF No. 109, at 31(internal quotations omitted) ("BMS Mem.").

[86] Compl., ¶¶41–42.

[87] *Luv n' Care, Ltd. v. Laurain*, No. 2022-1970, 2024 WL 1590593, at *8 (Fed. Cir. Apr. 12, 2024); *see Ohio Willow Wood Co. v. Alps S., LLC.*, 735 F.3d 1333, 351 (Fed. Cir. 2013) (collective weight of evidence of various misrepresentations made to the PTO supported a finding of deceptive intent); *Paragon Podiatry Lab'y, Inc. v. KLM Lab'ys, Inc.*, 984 F.2d 1182, 1190 (Fed. Cir. 1993) (deceptive intent "must generally be inferred from the facts and circumstances surrounding the applicant's overall conduct"); *see also Apotex Inc. v. UCB, Inc.*, 763 F.3d 1354, 1362 (Fed. Cir. 2014) (courts must consider a person's acts in the aggregate when determining intent to deceive the PTO).

able to trick the examiner into withdrawing his/her prior rejection, does not wipe the slate clean of their previous misrepresentations and/or omissions.

c. End payors have standing to bring *Walker Process* claims.

BMS asserts that end payors[88] lack standing to bring antitrust claims based on *Walker Process* theories. This is a plain misstatement of law.[89] In its *Walker Process* decision, the Supreme Court rejected arguments trying to limit the type of plaintiffs who have standing to bring antitrust claims premised on fraud on the PTO. There, defendants argued a competitor lacked standing to bring antitrust claims because it didn't have standing to otherwise invalidate the patent.[90] The Supreme Court noted it had allowed injured parties to "attack the misuse of patent rights" since at least 1944;[91] And held that "permit[ting] recovery of treble damages for the fraudulent procurement of the patent coupled with violations of [Section 2 of the Sherman Act]" would promote the public's "paramount interest in seeing that patent monopolies spring from backgrounds free from fraud or other inequitable conduct and that such monopolies are kept within their legitimate scope."[92]

BMS relies on the direct purchaser decision of *In re DDAVP Direct Purchaser Antitrust Litig.*, which outlines a set of factors that courts can consider when determining a party's standing.[93]

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[88] BMS use the term "indirect purchasers" to refer to end payors in their brief.

[89] *See, e.g.*, *In re DDAVP Indirect Purchaser Antitrust Litig.*, 903 F. Supp. 2d 198, 217 (S.D.N.Y. 2012) ("state-law Walker Process-type antitrust and/or consumer protection law claims are not preempted"); *Restasis*, 355 F. Supp. 3d at 150; *In re Lipitor Antitrust Litig.*, 336 F. Supp. 3d 395 (D.N.J. 2018); *Loestrin*, 261 F. Supp. 3d at 357 ("[S]tate law claims based on Walker Process-type fraud do not frustrate the purposes or objectives of federal patent law for the same reasons their federal counterparts do not.").

[90] *Walker Process Equipment*, 382 U.S. at 175.

[91] *Walker Process,* 382 U.S. at 176 (citing *Mercoid Corp. v. Mid-Continent Investment Co.*, 320 U.S. 661 (1944)).

[92] *Walker Process,* 382 U.S. at 177 (quoting *Precision Instrument Mfg. Co. v. Automotive Maintenance Machinery Co.*, 324 U.S. 806, 816 (1945)).

[93] While purchasers argue that they have standing to assert all claims raised, the Court need not decide this issue until class certification. *See DDAVP*, 903 F. Supp. 2d at 213 ("Generally, an Article III court must determine that it has jurisdiction over a plaintiff at the outset of a case. But the Supreme Court has carved out an exception to that rule when class certification issues are "logically antecedent to Article III concerns… there has been a growing consensus among district courts that class certification is 'logically antecedent,' where its outcome will affect the Article III standing determination, and the weight of authority holds that in general class certification should come first… I join the courts

However, that case does not hold that end payors cannot allege *Walker Process* fraud; that case only addressed direct purchaser standing (and allowed the case to proceed). Rather, in the indirect purchaser case of *In re DDAVP Indirect Purchaser Antitrust Litig.*— which BMS fails to mention in its motion to dismiss brief—this Court sustained the end payors' *Walker Process* fraud allegations.[94]

The Second Circuit considered *Walker Process* claims brought by end payers in *Cipro*; it did not throw those claims out for lack of standing.[95] Nor did the three circuit courts that have addressed *Walker Process* theories brought by end payers.[96] None even addressed the issue. Because BMS cannot direct the Court to any on-point Second Circuit decision holding that end payors lack standing[97]—and this district has held the opposite—BMS's argument fails.

2. The complaint adequately alleges Celgene pursued sham litigation.

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in that growing consensus and find that class certification is logically antecedent to the issue of standing in this case." (internal citations omitted)).

[94] *DDAVP*, 903 F. Supp. 2d at 217 ("As the Second Circuit in this case found, Plaintiffs have adequately pleaded the "intent to deceive" and "materiality" elements of a Walker Process fraud claim."). BMS's reliance on *Faraq v. Health Care Serv. Corp.* is also misplaced; *Faraq* stands for the unremarkable notion that "Walker Process standing should be interpreted in light of regional circuit law on antitrust standing." *Farg v. Health Care Service Co.*, No. 17-2547, 2017 WL 2868999, at *5 (N.D. Ill. July 5, 2017).

[95] The Second Circuit transferred end payers *Walker Process* claims to the Federal Circuit. *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 2007 U.S. App. LEXIS 30732, at *1 (2d Cir. Nov. 7, 2007). Post-*Actavis*, the Third Circuit held it need not transfer Walker Process, sham litigation, and reverse payment theories to the Federal Circuit. *In re Lipitor Antitrust Litig.,* 855 F.3d 126, 148 (3d Cir. 2017) (noting "[n]ow that the Supreme Court has confirmed that it is usually unnecessary to litigate these patent-law issues to determine antitrust liability, the development of post-*Actavis* jurisprudence is, in the ordinary case, left to the regional Courts of Appeals.").

[96] *Lipitor*, 868 F.3d at 266 (addressing *Walker Process*, sham litigation, and reverse payment theories and holding it was error for the district court to dismiss end payer and direct purchaser plaintiffs' allegations that Pfizer fraudulently procured and enforced the '995 patent); *United Food & Com. Workers Unions & Emps. Midwest Health Benefits Fund v. Novartis Pharms. Corp.*, 902 F.3d 1, 8–9 (1st Cir. 2018) ("*Gleevec*") (addressing *Walker Process* and sham litigation theories, no discussion of end payer standing, holding end payers failed to allege materiality); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1341 (Fed. Cir. 2008) (addressing *Walker Process*, sham litigation, and reverse payment theories transferred from the Second Circuit, no discussion of end payer standing; held no fraud occurred), abrogated by *F.T.C. v. Actavis, Inc.*, 570 U.S. 136, 133 S. Ct. 2223, 186 L. Ed. 2d 343 (2013).

[97] Only one Second Circuit case cited by BMS to bolster its assertion that indirect purchasers lack standing to allege Walker Process fraud actually pertains to Walker Process fraud. *See In re Cireprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514 (E.D.N.Y. 2005); *but see DDAVP*, 903 F. Supp. 2d at 217 ("Plaintiffs argue that cases like *Ciprofloxacin* and *K-Dur* were wrongly decided, and their arguments have some force. I need not go so far as to agree, however, in order to uphold their claims."). All other Second Circuit cases cited by BMS in support of their standing argument do not involve claims of *Walker Process* fraud. *See In re Am. Express Anti-Steering Rules Antitrust Litig.*, 19 F.4th 127, 134 (2d Cir. 2021); *Schwab Short-Term Bond Mkt. Fund v. Lloyds Banking Grp. PLC*, 22 F4th 103, 109 (2d Cir. 2021); *In re Aluminum Warehousing Antitrust Litig.*, No. 13-md-2481 (KBF), 2014 WL 4277510, at *1 (S.D.N.Y. Aug. 29, 2014).

a. *PRE* and *Primetime* define when conduct constitutes sham litigation.

Sham patent litigation is a well-established exception to the *Noerr-Pennington* doctrine, under which private entities are typically immune from antitrust liability based on a party's commencement of a prior court proceeding or concerted efforts incident to litigation.[98] In *Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus.* ("*PRE*"),[99] the Supreme Court held that a lawsuit is a sham if it is (1) "objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits"; and (2) subjectively motivated by a desire to "conceal[] 'an attempt to interfere directly with the business relationships of a competitor' through the 'use of the governmental process . . . as an anticompetitive weapon.'"[100] A litigant enjoys *Noerr-Pennington*'s limited immunity from antitrust liability only when it "could realistically expect success on the merits" of the petition – that is, if the litigation is "reasonably calculated" to elicit a "favorable outcome" or obtain "favorable relief."[101] If the first step is met, the court then examines the litigant's subjective motivation, focusing on "whether the baseless lawsuit conceals 'an attempt to interfere *directly* with the business relationships of a competitor.'"[102] BMS has not challenged the complaint's allegations that suits against generics were intended to interfere with competition.

The Supreme Court and Second Circuit apply a lesser standard for serial petitioning; both hold that serial petitions filed with the subjective intent to interfere with competition can be a sham

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[98] *See DDAVP,* 585 F.3d at 685–686 (*citing E.R.R. Presidents Conf.,* 365 U.S. at 127 and *United Mine Workers of Am. v. Pennington*, 381 U.S. 657 (1965)); *see also California Motor Transport Co. v. Trucking Unlimited*, 404 U.S. 508, 510 (1972) (extending *Noerr-Pennington* immunity to right of access to courts). The *Noerr-Pennington* doctrine "derives from two antitrust cases decided by the Supreme Court, and is rooted in First Amendment principles." *Mosdos Chofetz Chaim, Inc. v. Vill. Of Wesley Hills*, 701 F.Supp.2d 568, 594 (S.D.N.Y. 2010).

[99] 508 U.S. 49 (1993).

[100] *Id.*, 508 U.S. at 60–61 (quoting *Noerr*, 365 U.S. at 144 & *Columbia v. Omni Outdoor Advertising, Inc.*, 499 U.S. 365, 380 (1991)); *see also DDAVP*, 585 F.3d at 686 (acknowledging that the sham petitioning exception to *Noerr-Pennington's* limited antitrust immunity extends to sham citizen petitions to the FDA); *Primetime 24 Joint Venture v. Nat'l Broad. Co. Inc.*, 219 F.3d 92, 100–101 (2d Cir. 2000).

[101] *PRE*, 508 U.S. at 60–62; *see also id.* at 56.

[102] *Id.* at 61 (emphasis in *PRE*). As the Second Circuit puts it, "A single lawsuit can violate antitrust law as long as it is both an objective and subjective sham." *DDAVP*, 585 F.3d at 686.

even if individual petitions are *not* objectively baseless.[103] So too hold the Third, Fourth, and Ninth Circuits.[104] In the Second Circuit, the standard for the serial-petitioning exception is "whether the legal challenges are 'brought pursuant to a policy of starting legal proceedings without regard to the merits and for the purpose of injuring a market rival.'"[105]

Whether the sham litigation exception to *Noerr-Pennington* immunity applies is often a question of fact to be decided by the jury.[106] A court may decide the issue "as a matter of law" only where "there is no dispute over the predicate facts underlying the legal proceeding."[107] Courts in this circuit consistently refrain from making such a merits-related determination at the motion to dismiss

[103] *California Motor Transp. Co.*, 404 U.S. at 511 & 513 (holding "a pattern of baseless, repetitive claims" can constitute sham petitioning when it "leads the factfinder to conclude that the administrative and judicial processes have been abused."); *Otter Tail Power Co. v. U.S.*, 410 U.S. 366, 380 (1973) (noting *California Motor* defined sham litigation as "evidenced by repetitive lawsuits carrying the hallmark of insubstantial claims."); *PrimeTime 24 Joint Venture*, 219 F.3d at 92.

[104] *Hanover 3201 Realty, LLC v. Village Supermarkets, Inc.*, 806 F.3d 162, 179–80 (3d Cir. 2015) (noting court should perform "holistic review that may include looking at the defendant's filing success" as "circumstantial evidence of the defendant's subjective motivation," along with "other evidence of bad-faith"); *Waugh Chapel South, LLC v. United Food & Commercial Workers Union 27*, 728 F.3d 354, 364 (4th Cir. 2013) (focusing the analysis on the "pattern of the legal proceedings, not their individual merits"); *USS-POSCO Industries v. Contra Costa County Building & Construction Trades Council, AFL-CIO*, 31 F.3d 800, 804 (9th Cir. 1994) ("the fact that a small number in the series of lawsuits turn out not to be frivolous will not be fatal to a claim under *California Motor Transport*; even a broken clock is right twice a day"). The Tenth Circuit has not directly addressed this issue. *See CSMN Inv., LLC v. Cordillera Metropolitan Dist.*, 956 F.3d 1276 (10th Cir. 2020) (case outside of antitrust context, acknowledging *California Motor* and *Waugh Chapel*).). The First and Seventh Circuits have applied the *PRE* standard to serial petitioning, though the First Circuit's decision leaves open whether a lesser standard may apply to serial petitioning with different facts. *Puerto Rico Tel. Co., Inc. v. San Juan Cable LLC*, 874 F.3d 767, 768 (1st Cir. 2017); *U.S. Futures Exch., LLC v. Bd. of Trade of the City of Chicago*, 953 F.3d 955 (7th Cir. 2020).

[105] *PrimeTime 24 Joint Venture*, 219 F.3d at 101 (adopting standard articulated by Ninth Circuit and noting it is immaterial that some claims might "as a matter of chance" have merit); *see also In re Fresh Del Monte Pineapple Antitrust Litig.*, No. 04-MD-1628, 2007 WL 64189, at n. 19 (S.D.N.Y. Jan. 4, 2007), *aff'd sub nom. Am. Banana Co. v. J. Bonafede Co.*, 407 Fed. Appx. 520 (2d Cir. 2010) (citing standard in discovery motion context); *Blue Cross & Blue Shield of Vermont*, 2024 WL 323775, at *20 (citing standard in motion to dismiss context and noting that "at the present stage" of the case, the court could not "conclude that the serial-petition exception is inapplicable").

[106] *Sanborn Library, LLC v. Eris Info. Inc.*, No. 19-cv-2049, 2021 U.S. Dist. LEXIS 165496 (S.D.N.Y. Aug. 30, 2021) (observing "courts in this District" have "recognized that the applicability of the sham exception is often regarded as a question of fact for the jury, and ha[ve] repeatedly denied motions to dismiss sham litigation claims") (internal citations omitted); *See Restasis*, 333 F. Supp. 3d at 154–155 ("whether a citizen petition is a sham is generally a question of fact for the jury"); *Blue Cross & Blue Shield of Vermont*, 2024 WL 323775, at *15 ("Significant authority suggests the applicability" of the sham exception for the jury) (listing cases).

[107] *In re Elysium Health-Chromadex Litig.*, 354 F. Supp. 3d. 330, 336 (S.D.N.Y. 2019).

stage.[108] At least seventeen generic delay antitrust cases premised on Hatch-Waxman litigation recognize the sham litigation exception to *Noerr-Pennington* immunity, denying motions to dismiss.[109]

b. The defendants filed multiple waves of sham litigation.

Between May 2017 and March 2020, Celgene and later BMS filed multiple lawsuits against all generic Pomalyst ANDA filers alleging infringement of nine Pomalyst patents. The defendants knew they had no realistic chance of succeeding in the patent infringement litigation but pursued it to block the generics' ability to enter the market with generic Pomalyst. Absent the sham lawsuits, more affordable generic Pomalyst would have been available sooner.[110]

Beginning in May 2017, Celgene filed a first wave of patents litigation as to four patents. In its initial lawsuits against the ANDA filers, Celgene asserted the three pomalidomide method of treatment patents (the '262, '428, and '3939) and the only then-existing formulation patent (the '427).[111] A reasonable pharmaceutical company in Celgene's position could not realistically expect to succeed on the merits of these lawsuits.[112] The method patents were fraudulent and also manifestly obvious over prior art,[113] which disclosed, *inter alia*: thalidomide and its analogs to overcome drug resistance of multiple myeloma cells; efficacy of thalidomide with dexamethasone to specifically treat resistant multiple myeloma; the amount of dexamethasone plus thalidomide for such treatment; pomalidomide for the treatment of multiple myeloma; and pomalidomide to treat multiple myeloma

[108] *See* n. 69, *supra*.

[109] *See* Attachment 1.

[110] Compl., ¶3. The purchasers acknowledge that market entry before conclusion of the patent litigation would require at-risk entry. *See id.*, ¶¶31, 311; *but see id.*, ¶274 (noting the filing of the Fall 2018 lawsuits regarding '467 did not trigger a 30 month stay because '467 did not exist at the time those ANDAs were filed).

[111] Compl., ¶¶250–251, 276–278, 286–288.

[112] Compl., ¶¶252–253; *see also supra,* §IV(B)(2)(a) (regarding '262), §IV(B)(2)(b) (regarding '428 and '3939), and §IV(B)(2)(c) (regarding '427).

[113] Compl., ¶¶252–253; *see* 35 U.S.C. §102 (containing the conditions for patentability, including the definition of "prior art").

and relapsed/resistant disease.[114] A reasonable pharmaceutical company in Celgene's position could not realistically expect to succeed on a claim that the patents were valid and infringed. The June 2020 *Markman* decision eliminated any continued pretense the patents were valid.[115]

Celgene's infringement claims as to the '427 patent were similarly baseless because the patent was obtained by fraud[116] and because the ANDA filers, all experienced generic manufacturers in the business of regularly bringing generic products to market, routinely design around patents like the '427 that claim basic combinations of ingredients and lack any kind of complexity (such as bioequivalence metrics).[117] Celgene knew it could not prevail on a claim the '427 was infringed, but pursued the litigation to interfere with generics' ability to launch generic Pomalyst.

Between September 2018 and January 2019, Celgene filed a second wave of sham litigation as to the '467. As with the first wave of patent infringement litigation, a reasonable litigant could not expect to prevail on a claim that the '467 formulation patent was valid and infringed, because it (like the '427 formulation patent) was obtained through fraud, invalid as obvious over the prior art, and easily designed around to avoid infringement. Celgene did not expect success; its intent was to use the *litigation process itself* to delay generic competition by creating hurdles for the generics.[118]

Between February and April 2019, Celgene filed a third wave of sham litigation as to the crystal form patents. On December 20, 2017, months after the generics filed their ANDAs, Celgene filed patent applications that would lead to the pomalidomide crystal form patents. On October 9, 2018, the PTO allowed those patents to issue (the '647, '648, and '649); and on February 14, 2019, Celgene

[114] Compl., ¶120 (thalidomide analogs to overcome drug resistance); ¶¶124–128 (thalidomide with dexamethasone to treat multiple myeloma); ¶129 (dexamethasone dose); ¶¶131, 133–137 (pomalidomide to treat multiple myeloma); ¶¶132, 175 (pomalidomide to treat multiple myeloma and relapsed/refractory disease).

[115] Compl., ¶¶94–95.

[116] Compl., ¶¶201–216, 218, 251; *see also supra* Section IV(B)(1)(a).

[117] Compl., ¶256.

[118] Compl., ¶275.

began suing ANDA filers for infringement of those newly issued patents. Celgene had no colorable basis to assert that patents applied for *after* the generic companies had already developed their ANDA products and served paragraph IV notices were somehow novel over what came before (and therefore valid) and simultaneously infringed by what came before.[119] Even if the patents were valid, no reasonable pharmaceutical company could expect to prevail on claims that all three crystal form patents were infringed by eight different Pomalyst ANDA products. The '647, '648, and '649 patents each claim a different hydrate form of pomalidomide (a dihydrate, hemihydrate, and monohydrate, respectively).[120] To infringe all three patents, an ANDA product would have to be comprised of three different hydrates. If all hydrate forms were likely to be present in a single pomalidomide drug product, then why did Celgene patent each hydrate separately? And Celgene makes the same assertion as to all eight ANDA products, meaning each and every ANDA product would have to be a combination of all three (separately patented) hydrates. This is not typically the way pharmaceutical companies manufacture drug products, and it is exceedingly unlikely that eight generic manufacturers acted in this aberrant way in formulating their Pomalyst ANDA products.

Celgene could not have realistically expected to prevail on its claims that the crystal form patents were valid and infringed.[121] Instead, Celgene sought and asserted these patents solely to interfere with and inject delay in a generic Pomalyst launch.

In March of 2020, Celgene filed a fourth wave of sham litigation as to the '5939. The '5939, which is nearly identical to the earlier formulation patents, is subject to terminal disclaimers as to those patents, and is unenforceable for the same reasons. Celgene had no colorable claim these patents

[119] Compl., ¶320; *see also id.* ¶263 (listing application date and priority date for each patent), ¶266 (Celgene applied for these three patents approximately nine months after receiving seven paragraph IV letters describing the generic Pomalyst ANDA products in detail).[120] *See* Compl., ¶¶265, 284.

[120] *See* Compl., ¶¶265, 284.

[121] Compl., ¶284–285.

would be infringed by savvy generics, which would design around these rudimentary patents.[122]

Celgene filed iterative lawsuits, not because it believed it could or would prevail in the patent litigation, but rather to interfere with the generics' attempt to gain market entry and to thwart competition.[123] Celgene, and later BMS, knew the multiple waves of patent litigation were meritless but pursued the lawsuits to block generic entry. Celgene achieved its objective: unwarranted delay in generic Pomalyst entry. BMS acknowledged as much, stating (during the quarter BMS reported the Pomalyst litigation resolved) that BMS now had a "longer than previously expected market exclusivity for Pomalyst."[124]

The waves of sham litigation show a disregard for the merits and anticompetitive intent, satisfying the *PrimeTime* standard. Further, the purchasers have pled facts to support that the suits filed by Celgene (continued by BMS) were objectively baseless and intended to cause harm using a governmental process. The complaint alleges the defendants intended to interfere directly with the business of their competitors through this process, and thus satisfy both prongs of the two-part inquiry under *PRE*. To the extent any question remains whether this was sham litigation, that factual dispute should be deferred for determination by the jury on a full factual record.

c. Settlement does not immunize against a finding of sham litigation, nor can BMS overcome the well pled allegations by disputing facts.

Resolving patent litigation through settlement does not immunize against a finding of sham litigation. BMS asserts that the challenged lawsuits were not, as a matter of law, a sham because they ended in a settlement.[125] But the Second Circuit holds that even winning a lawsuit does not definitively

[122] Compl., ¶¶272, 294–295.

[123] *See* Compl., ¶¶275, 278, 285, 289, 296.

[124] Compl., ¶¶368, 371.

[125] *See* BMS Mem., 44–48.

demonstrate that the lawsuit was not a sham.[126] Numerous generic delay antitrust cases alleging sham theories have survived a motion to dismiss where the underlying patent litigation resulted in a settlement;[127] and many of those settlements were subsequently separately challenged as anticompetitive (as here). No case holds – at least Celgene cites none, nor can the purchasers find any – that a settlement precludes a finding of sham litigation.

BMS's attacks on the sham allegations are factual disputes not appropriate for resolution at the pleading stage. BMS raises disputes of fact regarding the sham allegations, but a court may only decide the applicability of the sham exception if there is no dispute regarding the facts in the underlying legal proceeding. The purchasers' sham allegations should be sustained.

C. The complaint alleges BMS made large, unjustified payments to generics.[128]

To state a reverse payment claim, the complaint must allege monopoly power (uncontested here) and a "large and unjustified" payment from the brand to the generic.[129] "At base, reverse payments violate antitrust law when they unjustifiably seek to 'prevent the risk of competition.'"[130]

A plaintiff need only "allege facts sufficient to support the legal conclusion that the settlement at issue involves a large and unjustified reverse payment;" A plaintiff can satisfy "this pleading standard without describing in perfect detail the world without the reverse payment,

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[126] *T.F.T.F. Capital Corp. v. Marcus Dairy, Inc.*, 312 F.3d 90, 94 (2d Cir. 2002) (holding that the win (on a default judgment) did not foreclose the possibility that the suit was a sham under the *Noerr-Pennington* exception); *see also Wellbutrin*, 749 F. Supp. 2d at 263–267 (denying dismissal of sham litigation allegations, even though manufacturer prevailed on one of its patent infringement claims).

[127] *See e.g., Restasis*, 333 F. Supp. 3d at 152, 154–155 (involving sham litigation, citizen petition, and patent misuse); *Lipitor*, 868 F.3d at 273 (reinstating sham and reverse payment allegations); *Loestrin*, 261 F.Supp.3d at 322, 348–349.

[128] The complaint does not allege a stand-alone reverse payment claim; it alleges the settlement is part of the monopolization scheme. Whether or not the payment is large/unjustified, the settlement's terms and consequences flow from the patent fraud and sham litigation aspects of that scheme and prolongs the consumer harm.

[129] *F.T.C. v. Actavis*, 570 U.S. 136, 158 (2013). The complaint alleges monopoly power. Compl., ¶¶396, 408.

[130] *Lipitor*, 868 F.3d at 250–251 (quoting *Actavis*). *See also FTC,* 976 F.3d at 352 (where "'a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement'. . . the payment is not justified.") (quoting *Actavis*).

calculating reliably the payment's exact size, or preempting every possible explanation for it."[131] Requiring a higher burden would "impose a nearly insurmountable bar for plaintiffs at the pleading stage because very precise and particularized estimates of fair value and anticipated litigation costs may require evidence in the exclusive possession of the defendants, as well as expert analysis."[132]

This Court holds that whether a payment is sufficiently large and unjustified to trigger antitrust liability is an "intrinsically fact-based determination" that "cannot be made on a pre-answer motion to dismiss." Rather, "[d]iscovery is needed."[133] This Court therefore sustains reverse payment allegations on motions to dismiss, even where the plaintiffs alleged "only summarily, that the early-settlement terms delayed generic entry."[134]

Regardless of the form or payment, the inquiry is the same: is the brand making a large, unjustified payment to generics to avoid the risk of competition?

Splitting monopoly profits on one drug in return for delaying entry of another drug constitutes an unlawful reverse payment. In evaluating side deals, courts assess whether the circumstances "suggest that the agreement may have been a means of masking value transferred in exchange for eliminating the risk of competition."[135] Agreeing to split monopoly profits on drug A in return for delay in generic entry for drug B is a recognized form of payment.[136] In FTC's recent case against Abbvie, the FTC alleged

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[131] *FTC*, 976 F.3d at 351 (internal quotations omitted).

[132] *Loestrin*, 814 F.3d at 552 (internal quotations omitted).

[133] *Sergeants Benevolent Assoc. Health & Welfare Fund v. Actavis,* No. 15-cv-7488 (CM), 2016 WL 4992690, *at 14 (S.D.N.Y. Sept. 13, 2016) ("*Namenda I*") (denying motion to dismiss re federal claims). *See also In re Namenda Indirect Purchaser Antitrust Litig.*, No. 1:15-cv-6549, 2021 WL 2403727, at *26 (S.D.N.Y. June 11, 2021) ("*Namenda III*") (denying summary judgment because whether there was a large and unjustified reverse payment is an issue to be decided by a factfinder."). BMS suggests *Actos* establishes a more demanding standard (*see* BMS Mem., 8). But recent decisions from this Court (described above) recognize these fact-based determinations ought not be resolved before discovery. The allegations here exceed those in *Actos*. See Section IV(C)(2), *infra.*

[134] *E.g.*, *Namenda I,* 2016 WL 4992690, at *15.

[135] *In the Matter of Impax Labs., Inc.*, No. 9373, 2019 WL 1552939, at *21 (F.T.C. Mar. 28, 2019), aff'd 994 F.3d 484 (5th Cir. 2021).

[136] *See Loestrin,* 261 F.Supp.3d at 337 ("Plaintiffs have plausibly alleged . . . the Femcon promotional deal was part of an unlawful reverse payment . . . to induce [Lupin] to stay out of the Loestrin 24 market.").

the brand cut generics in on the brand's TriCor profits in return for delayed generic entry for Androgel.[137] The district court dismissed. The Third Circuit reversed, holding that where "the generic company agrees to delay entry until patent expiration" on one drug in return for which "the brand-name company agrees to split monopoly profits" on a different drug, the court must accept as true allegations that the agreements are "linked."[138] The court held the FTC "plausibly alleged the TriCor deal was a reverse payment" and sustained the allegations because "the settlement may have been something more than just an agreed-upon early entry—it may have been pay-for-delay."[139]

Although the brand and generics may try to disguise a pay-for-delay monopoly profit share agreement, the deal will be judged not on its form, but on its anticompetitive effect. A brand can (illegally) split monopoly profits with a generic by granting a volume-limited license on a different drug. In *Xyrem*, the plaintiffs alleged the payment included the brand granting later-filing generics a "low-single-digit" percentage of the market.[140] By allocating to the generic a fixed percentage of the market, a brand eliminated the generic's incentive to compete on price. The court sustained the allegations: "volume-limited licenses are plausibly anticompetitive market allocations that reduced output and raised prices."[141]

Most favored entry clauses are recognized as an unlawful reverse payment. A most favored entry clause assures a settling generic that no one else will get a better deal: e.g., even though Natco agreed to a particular entry date, if another generic gets to market sooner, Natco can enter then too. A most favored entry "plus" clause goes further, guaranteeing the best deal: the right to enter *before* others.[142]

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[137] *FTC*, 976 F.3d at 358.

[138] *See also Actavis*, 570 U.S. at 158 ("If the basic reason [for the payment] is a desire to maintain and to share patent-generated monopoly profits, then, in the absence of some other justification, the antitrust laws are likely to forbid the arrangement.").

[139] *FTC*, 976 F.3d at 359.

[140] *In re Xyrem (Sodium Oxybate) Antitrust Litig.*, 555 F. Supp. 3d 829, 845 (N.D.Cal. 2021).

[141] *Id.* at 870.

[142] *Staley v. Gilead Sciences Inc.,* 446 F.Supp.3d 578, 612 (N.D.Cal. 2020) ("a [most favored entry plus] clause guarantees a second filer that it will be in a worse position compared to the first filer even where there is no ANDA Exclusivity."); *see also id.* at 590.

Most favored entry clauses give value to the generic by "disincentiviz[ing] other generic manufacturers from litigating their patent claims and coming to market as soon as possible."[143] They are also a mechanism to enforce the collusive agreement; they carry the threat that, if triggered, there will be a return to competition and a corresponding loss of shared monopoly profits.[144]

Courts sustain allegations that most favored entry clauses (or "acceleration clauses") form part of an unlawful reverse payment.[145] "That a MFE and/or MFEP is deserving of antitrust scrutiny – especially compared to other kinds of MFN clauses – is underscored by the fact that the whole point of a MFE and/or MFEP is about entry, *i.e.*, when competition is allowed into a market."[146]

Resurrecting a forfeited 180-day exclusivity period is a recognized form of payment. Shoring up the risk that a first-filing generic forfeited its lucrative 180-day exclusivity period by resurrecting that exclusivity period contractually poses a substantial benefit to first filers. In *Gilead*, the court viewed the most favored entry plus clause as particularly pernicious where the deal resurrected "ANDA [e]xclusivity or at least some kind of exclusivity where it no longer applied."[147] The court sustained the reverse payment allegations, reasoning in part that, "[r]esurrection of exclusivity could arguably be a significant deterrent to second filers."[148] Even where the FDA determines (after the parties have settled) that the 180-day exclusivity period has not been forfeited, removing the *risk* of

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[143] *Xyrem*, 555 F. Supp. 3d at 860.

[144] *Id.* at 860–861 (such clauses "creat[e] a powerful threat") (internal quotations omitted). Empirical studies show acceleration clauses deter generic entry. *See e.g.*, Keith M. Drake & Thomas G. McGuire, Generic Entry Before the Agreed-Upon Date in Pharmaceutical Patents, 16 J. Competition L. & Econ. 188, 188 (2020).

[145] *Xyrem*, 555 F. Supp.3d at 861 (on motion to dismiss, holding that "acceleration clauses plausibly cause anticompetitive harm as part of an alleged reverse payment scheme"). *See also Loestrin*, 261 F. Supp.3d at 333–334 (same); *In re Sensipar (Cinacalcet Hydrochloride Tablets) Antitrust Litig.*, MDL No. 2895, 2020 WL 7022364, at *6 (D. Del. Nov. 30, 2020) (same).

[146] *Gilead Sciences, Inc.*, 446 F.Supp.3d at 610.

[147] *Id.* at 612.

[148] *Id.*

forfeiture—and thus the *risk* of competition—constitutes a payment.[149]

1. The complaint alleges BMS's reverse payments took three forms.

The complaint alleges the size of the payment ($300 million) and how it was calculated.[150] The complaint also alleges when generics would have launched absent the unlawful reverse payments (October 30, 2020); the length of delay (more than five years); and that patients and plans must pay monopoly prices for pomalidomide through at least the first quarter of 2026.[151]

The complaint alleges the payment exceeded the brand's avoided litigation costs.[152] The patents cannot explain the extended delay in generic entry;[153] they would not have impeded immediate generic launch upon final approval (October 2020). To stop that launch, BMS made large, unjustified payments to generics. The complaint alleges those payments took three forms.

First, BMS paid the Pomalyst ANDA filers by ensuring they would continue to share BMS's monopoly profits on Revlimid, thus maximizing profits on both drugs. Of the eight Pomalyst ANDA filers that maintained their challenges to the Pomalyst patents,[154] all had a volume-limited license for generic Revlimid (or their Pomalyst commercialization partner did). Many of the Revlimid and Pomalyst agreements were entered into concurrently.[155] Limited-volume licenses eliminate incentive to compete on price, because a generic cannot gain sales by dropping price.[156] The volume-limited

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[149] *Actavis,* 570 U.S. at 157 ('prevent[ing] the risk of competition . . . constitutes the relevant anticompetitive harm.").

[150] Compl., ¶¶338–341. As in *Loestrin*, the allegations about the size of the payment "represent rather precise estimates of the value of each component of the deal, given Plaintiffs have not had the benefit of discovery, accompanied by a step-by-step calculation of how they reached those figures." *Loestrin*, 261 F.Supp.3d at 338.

[151] *See* Compl., ¶¶1, 349–369, 370–374, 380, 406–407.

[152] Compl., ¶¶338, 347, 357.

[153] *See supra* Sections II(A), IV(B)(1)(a), IV(B)(2)(b).

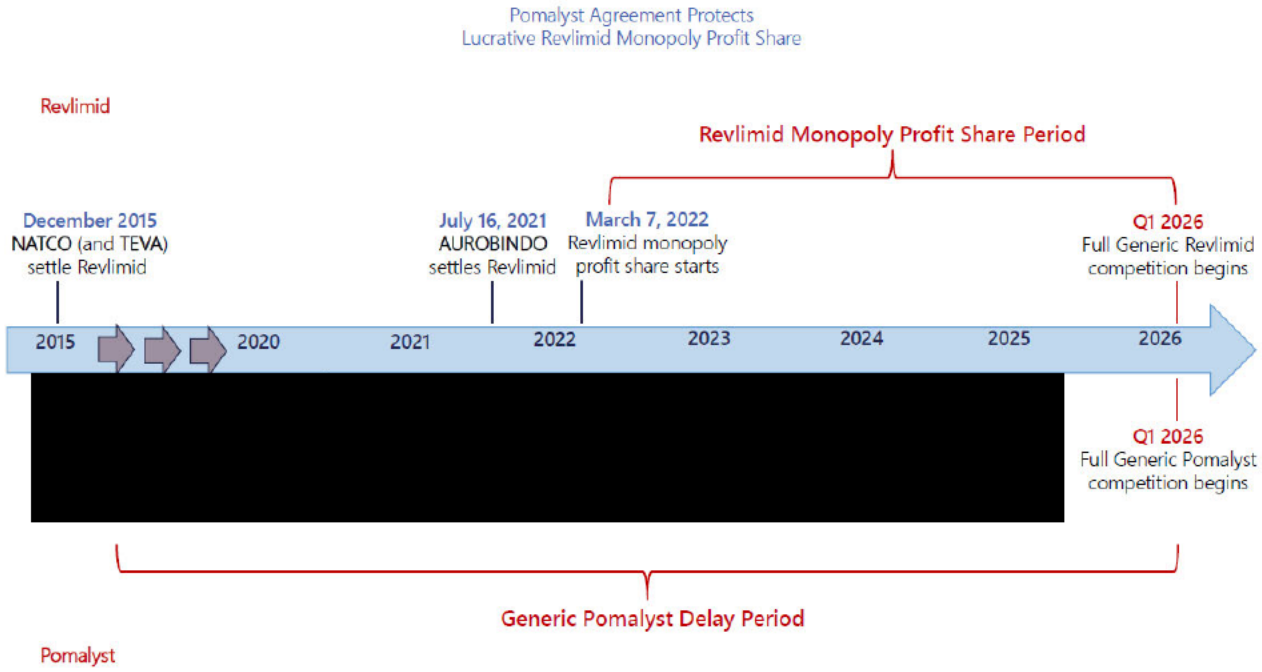
[154] *See* Compl., n. 100 (Par withdrew its paragraph IV letter early.).

[155] Alvogen, Apotex, and Hetero appear to have settled the Revlimid and Pomalyst patent litigations around the same time. *See* Compl., ¶367 (chart with publicly available date information).

[156] Compl., ¶¶325, 327, 349.

licenses operate as a monopoly profit share on Revlimid.[157] Teva conceded as much when it referred to the Revlimid settlement publicly as a "profit share."[158] The volume-limited licenses discipline generics to limit the sale of anything that could potentially take sales away from generic Revlimid. Had Natco or Aurobindo launched generic Pomalyst when they received final approval (in October 2020), there was a risk that generic Pomalyst could—at least theoretically—take some sales away from generic (and brand) Revlimid. Agreeing to delay generic Pomalyst until the Revlimid volume-caps end ensures BMS and the generics they will be able to milk maximum profits out of the Revlimid monopoly profit share.

Figure A[159]



Second, BMS paid generics by granting the first ANDA filers [redacted]

[redacted] Through the Pomalyst settlement agreements, [redacted]

[157] *See* Section II(B), *supra*. Compl., ¶326.

[158] Compl., ¶326.

[159] Enlarged version of graphic included as Attachment 2.

[redacted][160] These clauses transfer value to settling generics by disincentivizing others from continuing to litigate. And they enforce the collusive agreement: If a generic breaks away from the pack and launches, the risk of competition returns.[161]

Third, BMS [redacted]. The complaint alleges the first filers failed to obtain tentative approval within the specified time period, creating a risk they had forfeited the 180-day exclusivity period.[162] As of the time of the first Pomalyst settlement agreement ([redacted]), this uncertainty had not been resolved. [redacted]

Although the FDA *later* determined (after settlements had been inked) that there had not been a forfeiture, that later development is irrelevant.[163] What matters is that, at the time of settlement, the risk of forfeiture existed; and [redacted]

2. BMS's arguments for dismissing the reverse payment allegations fail.

The 2015 Actos decision neither controls nor supports dismissal. BMS relies primarily on the 2015 *Actos*[164] district court decision to argue the purchasers' reverse payment allegations should be dismissed. The argument fails for three reasons. First, *In Actos*, the Court reasoned that as of that time (2015), no other court had sustained claims that an acceleration clause was part of an unlawful payment, and pointed to the dismissal of similar allegations in *Loestrin*. Since that time, courts have sustained these allegations, and the dismissal decision on which the Actos court relied, *Loestrin*, was

[160] *See e.g.,* Greenblum Decl., ECF No. 111-3, Exhibit C (Teva Agreement). [redacted]

[161] *See Xyrem,* 555 F. Supp 3d at 860–861.

[162] Compl., ¶¶290–292.

[163] *Loestrin,* 261 F. Supp. 3d at 337 ("The deal must be valued at the time the parties entered the deal. . . .").

[164] *In re Actos End Payor Antitrust Litig.*, No. 13-CV-9244 (RA), 2015 WL 5610752, at *19 (S.D.N.Y. Sept. 22, 2015). BMS cites *In re Tamoxifen Citrate Antitrust Litig.,* 466 F.3d 187 (2d. Cir. 2006). Celgene' Mot. to Dismiss, 7–8. That holding was abrogated by *Actavis* and is no longer good law. *Actavis,* 570 U.S. at 146–147, 158.

subsequently reversed by the First Circuit.[165] Second, the purchasers' allegations far exceed those in *Actos*. There, the plaintiffs failed to allege monopoly pricing or shared monopoly profits; failed to adequately allege the payment was large and unjustified; and did "not explain the basis for those assertions, or offer any method of calculating the value of the licensing terms."[166] Third, subsequent decisions demonstrate the adequacy of the reverse payment allegations here, including this Court's decision in *Namenda*, as well as, e.g., *Loestrin, Xyrem,* and *Gilead.*[167]

BMS distorts the pleading requirements and misstates the law. First, noncash payments are actionable under *Actavis*.[168] Second, there is no heightened pleading standard for reverse payments.[169] Third, "the submission of the settlement agreement to the FTC [] does not protect the settlement agreement from antitrust scrutiny under *Actavis*."[170] Fourth, precise figures are not required at the motion to dismiss phase and, in any event, allegations the payment exceeded $300 million are sufficient.[171] Fifth, so-called early entry licenses are not "definitely lawful;"[172] As this Court

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[165] *See Loestrin*, 814 F. 3d at 538.

[166] *Actos*, 2015 WL 5610752, at *19.

[167] *Namenda I,* 2016 WL 4992690, at *14 (denying motion to dismiss DPP complaint); *Namenda III*, 2021 WL 2403727 (sustaining the plaintiffs' reverse payment allegations at summary judgment); *Loestrin,* 261 F.Supp.3d at 388 (sustaining reverse payment allegations); *Xyrem,* 555 F. Supp 3d at 863-865 (same); *Gilead,* 446 F.Supp.3d at 612 (same).

[168] *See*, *e.g.*, *Loestrin*, 814 F.3d at 548, 552 (District court dismissed for lack of a cash payment; First Circuit reversed); *King Drug Co. of Florence, Inc. v. Smithkline Beecham Co.,* 791 F.3d 388, 402–403 (3d Cir. 2015). BMS argues that "there was no 'nine figure' payment in any settlement" and "To be sure, Plaintiffs do not allege that Celgene paid the generics cash." BMS Mem., 7, 9.

[169] *See supra* n. 58. *Cf* BMS Mem., 7.

[170] *Lipitor*, 868 F.3d at 262. *See also* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 1117, 117 Stat. 2066, 2463 (2003) ("[A]ny failure of the [FTC] to take action" against a filed settlement agreement "shall not at any time bar any proceeding or any action with respect to" any such agreement); *In re Zetia (Ezetimibe) Antitrust Litig.*, No. 2:18-MD-2836, 2023 WL 4156858, at *4 (E.D. Va. Apr. 5, 2023) (precluding evidence at trial that FTC took no action re allegedly anticompetitive settlement agreement); Brief for FTC as Amicus Curiae, at 11, *In re Effexor XR Antitrust Litigation*, 15-1184 (3d Cir. Nov. 17, 2015) (stating "government inaction does not indicate agency approval" and noting decision to act requires balancing many factors, including Agency resources). *Cf* BMS Mem., 18, n. 11 (touting the submission of the agreements to the FTC).

[171] *See supra* n. 67. *See also Loestrin,* 261 F.Supp.3d at 333 (on remand, sustaining allegations acceleration clause formed part of the reverse payment, even though "EPPs [did] not attach a dollar figure to the acceleration clause.")

[172] *Namenda II*, 2018 WL 7197233, *17 (noting that the defendants failed to cite any "new, controlling case law which holds that, as a matter of law, early entry licenses are immune from antitrust scrutiny" and explaining that "all benefits conferred as part of a settlement agreement are subject to antitrust review under the Rule of Reason."). *See also*

recognizes, *Actavis* rejected the notion that a settlement that permits a generic to enter before patent expiry was per se legal.[173] Sixth, this Court has sustained, at the pleading stage and on summary judgment, allegations that a most favored entry (or "acceleration") clause formed part of an unlawful reverse payment,[174] as have other courts.[175] Courts reject the argument that most favored entry clauses are procompetitive.[176] As one former pharma executive testified before Congress, most favored entry clauses are "'poison pill' provisions" and "represent 'the primary anticompetitive aspects of settlements' insofar as they 'eliminate any incentive for a subsequent filer to continue to litigate for earlier market entry.'"[177]

The defendants mischaracterize the allegations. We address six examples. First, BMS argues "Plaintiffs plead [that] the generic challengers were worse off under the terms of the settlements."[178]

FTC, 976 F.3d at 359 ("Because the FTC plausibly alleged the TriCor deal was a reverse payment, the settlement may have been "something more than just an agreed-upon early entry"—it may have been "pay-for-delay."). None of the cases BMS cites support its argument that "it is definitively lawful for parties to compromise on [the entry] date." BMS Mem. at 10. For example, BMS relies on *King Drug Co. of Florence, Inc.*, 791 F.3d at 407–408, but the paragraph (from which BMS selectively quotes) states: "Although we agree that the Actavis 'Court expressly identified early-entry licensing as a traditional form of settlement whose legality the opinion took pains not to disturb,' [] a no-AG agreement *is no more solely an early-entry licensing agreement than the settlement in Actavis itself*, where entry was permitted 65 months before patent expiration. . . *Notwithstanding such "early entry," the antitrust problem was that, as the Court inferred, entry might have been earlier, and/or the risk of competition not eliminated, had the reverse payment not been tendered.*" *Id.* (emphasis added). The Third Circuit reversed the district court's grant of the motion to dismiss, reinstating the plaintiffs' reverse payment allegations.

[173] *Namenda I*, 2016 WL 4992690, at *15 ("the [Supreme] Court did not expressly hold that settlements that merely provide for the early-entry of a generic do not trigger antitrust scrutiny."). This Court has further explained that an agreement that generic entry will begin before termination of the last expiring patent "may appear to be proper under *Actavis*," but the "legality of these terms is better decided on a motion for summary judgment, after discovery has taken place." *Id.* at *14.

[174] *Namenda I,* 2016 WL 4992690 (denying motion to dismiss re federal claims); *Namenda II*, 2018 WL 7197233 (addressing motion to dismiss re state law claims); *Namenda III*, 2021 WL 2403727 (denying summary judgement as to antitrust claims). *Cf* BMS Mem., 12, 17.

[175] *See supra* n. 143–147 (citing *Gilead*, *Xyrem*, *Loestrin*, *Sensipar*).

[176] *See e.g., Gilead*, 446 F.Supp.3d at 610 (this argument "is problematic for at least three reasons: (1) it addresses only the MFE, and not the MFEP (which gives Teva a preferential entry date compared to other generic manufacturers); (2) it ignores Plaintiffs' theory that Teva agreed to a delayed entry date– i.e., a later date than it otherwise would have – because it was given, in exchange, the benefits afforded by both the MFE and MFEP; and (3) it ignores Plaintiffs' theory that the MFE/MFEP combination deterred second filers from trying to get an earlier entry date.")

[177] *Protecting Consumer Access to Generic Drugs Act of 2009: Hearing Before the Subcomm. on Commerce, Trade, and Consumer Protection*, H.R. 1706, 111th Cong., at 228 (2009) (statement of Bernard Sherman, CEO, Apotex, Inc.), available at http://www.gpo.gov/fdsys/pkg/CHRG-111hhrg67822/pdf/CHRG-111hhrg67822.pdf.

[178] BMS Mem. 9.

Not true. The purchasers allege that "[t]he enormous difference between the reasonably estimated returns . . . $167-$300 million over the first six months from imminent launch, versus about $19.4 million under the settlement . . . requires significant compensation to Natco/Breckenridge for the settlement."[179] No rational economic actor would give up hundreds of millions in profits from an immediate launch unless the deal with BMS put it in a *better* position than if it had launched. The purchasers allege the generics received "significant compensation" of at least $300 million to forgo launch and delay entry for more than five years.[180]

Second, BMS argues that "Plaintiffs' claims fail because their entire theory of the value of these alleged payments amounts to *when* the generic can sell its product—that is, the licensed entry date. But it is definitively lawful for the parties to compromise on that date. *See Actavis,* 570 U.S. at 158 . . . ."[181] That incorrectly construes the facts. The complaint alleges BMS paid generics with (i) protection of profits from an unlawfully allocated Revlimid market, (ii) [redacted] and (iii) [redacted][182] In return, the generics agreed to delay their entry for more than five years; absent the payment, generics would have entered earlier. To argue that the purchasers' "entire theory of the value of these alleged payments amounts to *when*

[179] Compl., ¶344.

[180] Compl., ¶¶338, 344, 347, 352, 361, 363. BMS attacks the at-risk launch allegations. *See* BMS Mem., at 7, 19. The complaint alleges generics would earn $300 million if they launched upon approval; and the patents would not impede such launch. *See supra* Sections II(A), IV(B)(1)(a), IV(B)(2)(b). *See, e.g.*, *In re Nexium (Esomeprazole) Antitrust Litig.*, 968 F.Supp.2d 367, 390 (D. Mass 2013) (denying motion to dismiss where theory of injury depended on at-risk launch); *In re K–Dur Antitrust Litig.*, 338 F.Supp.2d 517, at 535 (D.N.J. 2004) ("conjecture" that generic would not enter at-risk "is not this Court's concern on a motion to dismiss"); *Andrx Pharms. Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 809 (D.C. Cir. 2001) (reversing dismissal because a juror could conclude generic enter at-risk).

[181] BMS Mem., 10 (emphasis in original).

[182] Confusingly, BMS cites *In re Aggrenox Antitrut Litig.,* 94 F.Supp.3d 224, 243–245 (D. Conn. 2015), suggesting it supports an argument that the purchasers have not alleged a reverse payment. BMS Mem. 10. But the *Aggrenox* court sustained allegations regarding the same payment forms as alleged here, including side deals (i.e., licenses on two different drugs that were litigated separately and a "co-promotion" agreement) and anticompetitive contractual clauses (i.e., a "no-authorized generic" agreement). *Id.* at 236, 244–246.

the generic can sell its product" is simply not true (or, alternatively, it is true for *all* reverse payment settlements).

Third, BMS argues, "even if Plaintiffs' theory that 'the settlements must have been worth nine figures' worked as to Natco . . . Plaintiffs do not even attempt that [] mathematical exercise for either of the two other settlements (with Teva and Aurobindo) that Plaintiffs purport to challenge."[183] But the purchasers do allege the size of the payment to Aurobindo: "if both Natco/Breckenridge and *Aurobindo* . . . were to enter the market . . . . the presence of an additional generic would likely have caused some degree of additional price erosion. . . . each of the ANDA filers would still expect to earn about $167 million ($2.25 billion in 2021 U.S. sales x 0.5 years x 90% of the market is generic x 33% of generic market x 50% price of the brand)."[184] The complaint includes detailed facts alleging that the Teva settlement was a reverse payment.[185]

Fourth, BMS argues that the purchasers have made conflicting statements by alleging that Natco/Breckenridge and Aurobindo would have been the only ones who could launch on October 30, 2020, [redacted][186] There is no conflict. Natco/Breckenridge and Aurobindo were the first to receive final approval. They (and no one else) could launch generic Pomalyst on October 30, 2020. Each day they were on the market selling without competition from any other generic, Natco/Breckenridge and Aurobindo could charge higher prices and sell more product than if they were competing with a third generic. But if the FDA (i) concluded Natco/Breckenridge and Aurobindo had forfeited their potential exclusivity and (ii) granted other, later-filing generics final approval, then those generics could launch too. That entry would cause price, and profits, to fall. Natco/Breckenridge and Aurobindo were therefore

[183] BMS Mem., 20.

[184] Compl., ¶340 (emphasis added). *See also id.* at ¶¶353–363.

[185] Compl., ¶¶346–352.

[186] BMS Mem., 13.

highly incentivized to launch immediately *and* to take (illegal) steps to protect against the risk that they had forfeited the 180-day exclusivity period.

Fifth, BMS argues that the purchasers "claim that Celgene provided 'protection' against a 'risk' of forfeiture of 180-day exclusivity for only two (Natco and Aurobindo)" and that the purchasers "say nothing about the other" generics.[187] Again, not true. The purchasers allege that to "avoid forfeiture of the right to the 180-day statutory exclusivity" all first filers, including "Teva, Natco/Breckenridge, Apotex, Hetero, Par, Aurobindo, and Mylan," "were required . . . to obtain tentative or final approval of their application from the FDA by August 8, 2019. However, by August 8, 2019, none of the first filers had received tentative approval."[188]

Sixth, BMS, which is being sued in a different matter for unlawfully delaying generic Revlimid, argues that the purchasers "cannot bootstrap the existence of *those* claims into a basis to proceed *here*."[189] Here, the purchasers allege that, as part of an overarching monopolization scheme to delay generic *Pomalyst* entry: (a) Celgene fraudulently obtained *Pomalyst* patents; (b) BMS then asserted those fraudulent *Pomalyst* patents in sham litigation against *Pomalyst* ANDA filers; and (c) to further extend the delay in generic *Pomalyst* entry, BMS paid off the *Pomalyst* ANDA filers (only one piece of that payment relates to its Revlimid settlements). BMS is not immunized for its Pomalyst wrongdoing because it allegedly also engaged in an anticompetitive scheme concerning Revlimid.

D. The complaint alleges a monopolization claim against Mr. Insogna.

1. Attorneys can be liable under the Sherman Act and are not absolved by delay between the misconduct and the manifestation of harm to the plaintiff.

[187] BMS Mem., 12, 14. BMS argues "The predicate of Plaintiffs' theory, therefore, is that there is always a "risk" that a first-filer will fail to retain its statutory exclusivity, up until the moment the FDA makes an official statement to the contrary." *Id.* at 13. That may be true, but here the allegation is that there was a specific, existing risk of forfeiture created by the fact that the first filers had failed to obtain tentative approval within 30 months. Compl., ¶290–292.

[188] Compl., ¶¶290–291. *See also id.*, ¶¶366, 369.

[189] BMS Mem., 16 (emphasis in original).

"[I]t is firmly settled that officers and employees of a corporation 'may be held individually liable for corporate actions that violate the antitrust laws if they authorize or participate in the unlawful acts.'"[190] "The individuals through whom a corporation acts and who shape its intentions can be held liable on a charge of attempted monopolization."[191]

Courts hold that, while mistakes and run of the mill legal advice may not create liability, "if [the attorney] makes policy decisions for the corporation, then he subjects himself to liability for attempted monopolization as in the case of any executive officer of the company performing a similar function."[192] Such an executive officer "may be held liable under the Sherman Act to the extent that individual has 'participated in violations of' the antitrust laws, such as by 'negotiating, voting for[,] or executing agreements which constituted steps in the progress of the conspiracy.'"[193] Where the corporate officer or agent "participated in the anticompetitive conduct at issue, [and] also designed, implemented, and negotiated the network of contracts that block generic competition," such activity "is sufficient to subject them to liability for antitrust violations."[194]

Attorneys exceed the role of legal advisor where they "formulat[e] strategy in connection with the scheme to monopolize, . . . conspir[e] with one or more of the other Defendants to create, and becom[e] an active participant in and formulat[e] policy decisions in connection with, a continuing course of conduct . . . to monopolize and/or unfairly restrain trade."[195]

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[190] *Broad. Music, Inc. v. Hearst/ABC Viacom Entm't Servs.*, 746 F. Supp. 320, 330 (S.D.N.Y. 1990) (quoting *Brown v. Donco Enter., Inc.* 783 F.2d 644, 646 (6th Cir. 1986)).

[191] *Tillamook Cheese & Dairy Ass'n v. Tillamook Cnty. Creamery Ass'n*, 358 F.2d 115, 118 (9th Cir. 1966) (citing *U.S. v. Lorain Journal Co.*, 92 F. Supp. 794, 800 (N.D. Ohio 1950)); *Bergjans Farm Dairy Co. v. Sanitary Milk Prods*, 241 F. Supp. 476, 486 (E.D. Mo.1965); *Kentucky-Tennessee Light & Power Co. v. Nashville Coal Co.*, 37 F. Supp. 728, 738 (W.D. Ky. 1966)).

[192] *Id.*

[193] *Vyera Pharms. LLC*, 479 F. Supp. 3d at 50 (quoting *Hartford-Empire Co. v. U.S.*, 323 U.S. 386 (1945)).

[194] *Id.*

[195] *Jarrow Formulas, Inc. v. Int'l Nutrition Co.*, 175 F. Supp. 2d 296, 314–315 (D. Conn. 2001).

A cause of action accrues when the plaintiff begins suffering injury and a defendant is not absolved for earlier-in-time misconduct that caused that injury. For Sherman Act claims, there is no dispute that the statute of limitations is four years from when the "cause of action accrued," and an antitrust cause of action accrues "when a defendant commits an act that injures a plaintiff's business."[196] Even where an action commences more than four years after "the last anticompetitive act," courts have found Sherman Act claims timely, reasoning that otherwise, "damages could not then have been recovered by plaintiffs because their claims would not have been ripe for judicial resolution in view of the speculative nature of future conduct that might have thereafter occurred."[197]

Courts decline to time-bar allegations that an individual defendant "played a critical role in the design and execution of contracts at the heart of [a] scheme that remained in effect as of the date this action was filed" because "liability hinges not on his title, but on his involvement and participation in [defendant's] unlawful scheme."[198] "The fact that those foundational acts took place more than four years before the Direct Purchaser Plaintiff filed its complaint here is irrelevant."[199]

2. Insogna actively participated in the monopolization scheme.

Insogna orchestrated Celgene's scheme to fraudulently obtain patents and was an integral component of the overarching monopolization scheme. Insogna played a critical role in defrauding the PTO to unlawfully obtain two key pomalidomide patents for Celgene, the first step in the overarching scheme to

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[196] *Aggrenox*, 94 F. Supp. 3d at 237 (citing *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 401 U.S. 321, 338 (1971)).

[197] *Mayor & City Council of Balt. v. Actelion Pharms. Ltd.*, 995 F.3d 123, 125–126 (4th Cir. 2021). *See also In re Relafen Antitrust Litig.*, 286 F. Supp. 2d 56, 63–64 (D. Mass. 2003) (explaining the rationale of *Zenith*'s speculative damages accrual rule in sham litigation case: "To require such action would lead to the absurd result that vast numbers of potential antitrust plaintiffs would be required in every patent or business litigation to sue or intervene preemptively in those actions in the unlikely (but possible) event that the suit was filed fraudulently."); *Winkler-Koch Engineering Co. v. Universal Oil Products Co.*, 100 F. Supp. 15, 29 (S.D.N.Y. 1951) ("Where, as here, the suit is for the damages resulting from a single continuous wrong and from the cumulative effect of a contemplated series of acts designed to accomplish a common purpose and object, the cause of action did not accrue, and applicable limitations did not begin to run until the common purpose and object of the conspiracy had been achieved.").

[198] *Vyera Pharms. LLC*, 479 F. Supp. 3d at 52.

[199] *Namenda I*, 2016 WL 4992690, at *16.

unlawfully extend the pomalidomide monopoly. After Celgene procured a license to the D'Amato patent portfolio, Insogna took over management of that portfolio, and aided Celgene in dismantling it to hide invalidating prior art.[200] The complaint alleges with particularity Insogna's numerous material misrepresentations to the PTO, including (1) repeating and perpetuating the examiner's mistaken belief that the '517 patent does not teach pomalidomide; (2) failing to disclose that D'Amato (2001) taught methods of using pomalidomide to treat multiple myeloma, a fact he was aware of as the manager of D'Amato's patents; (3) misrepresenting and concealing that Davies (2001) taught pomalidomide to treat multiple myeloma and relapsed/refractory disease; (4) concealing that Schey (April 2002) taught the maximum daily dosage and therefore the claimed dosing ranges; and (5) falsely claiming that the '427 patent unexpected solved for stability issues.[201] But for Insogna's false representations and deliberate omissions before the PTO, the '262 method of treatment and '427 formulation patents would not have issued.[202]

Taken together, the allegations in the complaint show that Insogna—as patent counsel to Celgene for nearly 30 years now—was interconnected with Celgene's scheme to monopolize the pomalidomide market. He repeatedly lied to the patent office about the teachings of the prior art, concealed material prior art from the patent examiners, and, as power of attorney for Celgene as licensee to the D'Amato patents and patent applications, abandoned D'Amato's pomalidomide method of use patents and applications to reduce the risk they would impede Celgene's attempts to get newer, later-expiring pomalidomide patents. Insogna was integral in "formulating strategy in connection with the scheme to monopolize . . . and becoming an active participant in and

[200] Compl. ¶¶157–158, 182.

[201] Compl., ¶¶169–174 (the '517 false statements); ¶¶176–182 (D'Amato (2001) omission); ¶¶175, 196 (Davies (2001) misrepresentations and omissions); ¶¶135, 187, 196, 210 (Schey (April 2002) omissions); ¶¶212–215 (stability false statements).

[202] Compl., ¶¶195, 216.

formulating policy decisions in connection with, a continuing course of conduct . . . to monopolize."[203] Indeed, Insogna's law firm bio talks up his high-level role in formulating strategy for Celgene, boasting, "Anthony's patent strategies have protected several multimillion and multibillion dollar drugs including . . . Pomalyst®."[204]

The purchasers' claims against Insogna are timely. Insogna's fraudulent procurement of the '262 and '427 patents was the foundational act in Celgene's years-long scheme to delay generic entry through unlawful extension and enforcement of its patents. The acquisition of those fraudulent and invalid patents led directly to the paragraph IV litigation against the generics, which the purchasers allege then settled with a large, unjustified reverse payment to delay generic market entry.[205] Insogna's fraud was a time bomb, the effects of which the purchasers would not feel until October 30, 2020, when Aurobindo and Natco received final approval and yet failed to launch generic Pomalyst. The complaint alleges the critical role Insogna played in the design and execution of Celgene's scheme to unlawfully obtain pomalidomide patents.[206] His involvement and participation in the scheme led directly to harm to the purchasers.

3. Insogna's attempts to skirt liability—by downplaying his role in the scheme and arguing his involvement was too remote in time—fail.

First, Insogna cites a Sixth Circuit case, *Brown v. Donco*, for the proposition that *only* through allegations that an individual defendant "exerted his power and influence so as to direct the corporation to engage in the complained of acts for an anticompetitive purpose" can plaintiffs allege that he exceeded his role as a legal advisor.[207] But that cherry-picked language from *Brown* ignores

[203] *Int'l Nutrition Co.*, 175 F. Supp. 2d at 315.

[204] Insogna Biography, https://www.jonesday.com/en/lawyers/i/anthony-insogna?tab=overview (accessed 4/18).

[205] Compl., ¶455; *see supra* Sections IV(B)(2)(b), IV(C)(1).

[206] Compl., ¶¶67, 105–107, 142, 147, 150, 157–159, 163-167, 170–179, 181-195, 205–214, 412.

[207] Mem. of Law in Supp. of Anthony Insogna's Mot. to Dismiss, ECF No. 118, at 7 ("Insogna Mem.").

the several other statements of law that gibe with the general law that purchasers cite: individual liability under the antitrust laws can be imposed when the lawyer "becomes an active participant in formulating policy decisions with his client to restrain competition."[208] Moreover, the *Brown* court noted that the plaintiffs' complaint "failed to allege that the attorney defendants made policy decisions on behalf of their client or in any other way motivated Joe's catering to engage in litigation for an anticompetitive purpose."[209] But this is exactly what the purchasers allege: that Insogna knowingly and intentionally engaged in an anticompetitive scheme, with plausible and specific factual allegations of misrepresentations to the patent examiners, for an anticompetitive purpose.[210]

Insogna's statute of limitations argument, which rests on a misreading and misapplication of *Berkey Photo,* also fails. Insogna relies on *Berkey Photo* for the proposition that the "rule of accrual applies *only* to claims that the defendant overcharged for a product," and since Insogna "is not a monopolist and cannot 'overcharge' anyone,"[211] the purchasers' claims against him are time-barred. *Berkey Photo* asserts no such rule. The Second Circuit's discussion of § 15b was limited to monopolists simply because the one defendant in that case, Kodak, was alleged to be a monopolist; The court does not consider the application of the antitrust statute of limitations to a co-defendant alleged to have participated in the monopolist's overarching anticompetitive scheme.

In fact, *Berkey Photo* stands for the very rule purchasers advocate for: "the purchaser's claim cannot accrue until it actually pays the overcharge"; this is true even for "wrongful action occurring

[208] *Brown v. Donco Enter., Inc.* 783 F.2d 644, 646 (6th Cir. 1986).

[209] *Id.* at 647.

[210] Compl. ¶¶150, 158–159, 170–195, 210–216 (list of Insogna's material misrepresentations); *Id.* ¶¶412, 421, 449–450, 465–466 (alleging that Insogna's material misrepresentations were undertaken "to further the monopolization" and that he "knowingly and intentionally engaged in an anticompetitive scheme designed to block and delay entry of AB-rated generic versions of Pomalyst.").

[211] Insogna Mem., 16 (emphasis added).

before the limitations period but that nevertheless made an enduring contribution to the monopolist's ability to charge an excessive price."[212]

Given the unambiguous statement of law that the antitrust limitations period is tied only to accrual, Insogna's plea that his "last alleged act was in June 2013" is irrelevant.[213] "If merely an overt act [more than four years before accrual] without injury were to be the starting gate for limitations to run, then all those who would first suffer antitrust injury more than four years after that overt act 'would be forever incapable of recovery.'"[214] Because Insogna's anticompetitive actions—fraudulently obtaining the '262 method of treatment and '427 formulation patents through material misrepresentations to the patent examiners—did not ripen into a cause of action until the purchasers were overcharged in 2020, the claims against him are not time-barred.

E. The complaint alleges a monopolization claim against Zeldis, the claims are timely, and a decision on Zeldis's fact-based jurisdiction argument should await discovery.

The purchasers concede there is no injunctive and declaratory relief available to them from Zeldis under Section 2 the Sherman Act and withdraw that claim as to Zeldis only. The purchasers have adequately alleged monopolization claims against Zeldis under state law; and those claims are timely. The purchasers request that Zeldis's motion to dismiss for lack of personal jurisdiction be held in abeyance pending limited, expedited jurisdictional discovery.

1. The complaint alleges an unlawful monopolization claim against Zeldis.

The purchasers adequately allege that Zeldis participated in a scheme to monopolize the market for pomalidomide, including by defrauding patent examiners. Zeldis argues he should be dismissed because he was merely "the inventor named on patents that Plaintiffs allege were

[212] *Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263, 295 (2d Cir. 1979).

[213] Insogna Mem., 16.

[214] *Mayor & City Council of Balt.*, 995 F.3d at 131 (quoting *Zenith*, 401 U.S. at 340, 91 S. Ct. 795).

fraudulently procured,"[215] essentially a passive actor with no additional responsibility or culpability. Not true—Zeldis was in fact the *applicant* for these patents and as such had a duty to disclose all prior art known to him. The purchasers adequately allege he failed in that duty of candor.

An individual may be held liable under the Sherman Act "to the extent that individual has 'participated in violations of' the antitrust laws, such as by 'negotiating, voting for[,]or executing agreements which constituted steps in the progress of the conspiracy.'"[216] *In FTC v. Shkreli*, this Court rejected the individual defendants' argument that the monopolization claims against them should be dismissed: "Performing the activities described in the Amended Complaint as corporate officers and agents is sufficient to subject them to liability for antitrust violations."[217] Courts have held individuals liable for claims based on Section 2 of the Sherman Act.[218] Here, Count V deals specifically with monopolization laws of 28 other states. The purchasers allege that conduct violating the federal Sherman Act will, if proven, also establish a claim under the respective state laws.[219]

2. The claims are timely.

Zeldis argues the claims against him are time-barred for the same reasons advanced by Insogna. For the same reasons discussed above, the purchasers' claims against Zeldis are timely.[220]

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[215] Mem. of Law in Supp. of Zeldis Mot. to Dismiss, ECF No. 115, at 5 ("Zeldis Mem.").

[216] *Vyera Pharms, LLC*, 479 F.Supp.3d at 50 (quoting *Hartford-Empire Co. v. United States*, 323 U.S. 386, 407 (1945)). Zeldis cites a post-trial decision in the same case finding individual defendant liable where he "conceived of, implemented, maintained, and controlled" the "anticompetitive and monopolistic scheme" through management and policy direction. Zeldis Mem., 14, citing *FTC v. Vyera Pharms, LLC*, 581 F.Supp.3d 579, 637–638 (S.D.N.Y. 2002).

[217] *Vyera Pharms, LLC*, 479 F. Supp.3d at 50.

[218] *See Vyera Pharms, LLC*, 581 F.Supp.3d at 637; *Brown,* 783 F.2d at 646 (stating individual liability can be "imposed only where corporate agents are actively and knowingly engaged in a scheme designed to achieve anticompetitive ends"); *Tillamook County Cheese*, 358 F.2d at 118 (stating in civil liability case based on Section 2 that individuals "through whom a corporation acts and who shape its intentions can be held liable on a charge of attempted monopolization"); *Kansas City Star v. United States*, 240 F.2d 643, 664 (8th Cir. 1957) (holding advertising manager and employer newspaper liable for Section 2 violations).

[219] Compl., ¶462.

[220] *See* Section IV(D)(1), *supra.*

3. Having identified a "genuine issue of jurisdictional fact," the purchasers seek limited discovery of Zeldis; and propose the motion be held in abeyance.

First, the purchasers recognize their prior error in interpreting the law of personal jurisdiction and a resulting misrepresentation of the law to the court. In our pre-motion letter and during the pre-motion conference, the purchasers asserted that owning property in New York was sufficient to establish personal jurisdiction under § 302(a)(4) of the New York long-arm statute. Upon further examination of the statute and the case law, the purchasers acknowledge that mere ownership of property is insufficient and that something more is necessary, *i.e.*, the cause of action must arise out of the ownership, use or possession of the property.[221] While purchasers believe the Court has jurisdiction over Zeldis, we apologize for the erroneous statement to the Court.

To survive a motion to dismiss for lack of personal jurisdiction when the court has not held an evidentiary hearing, a plaintiff "need only make a prima facie showing of jurisdiction through affidavits and supporting materials to satisfy this burden."[222] A court must "construe the pleadings and any supporting materials in the light most favorable to the plaintiff[]."[223]

In assessing personal jurisdiction, courts conduct a two-part analysis. A court deciding a motion to dismiss for lack of personal jurisdiction performs a two-part analysis, "first determining whether there is a statutory basis for exercising personal jurisdiction, . . . and second deciding whether the exercise of jurisdiction comports with due process."[224] Under the first prong, the plaintiff must allege facts sufficient to plausibly show the State's long-arm statute is satisfied. Under New York's

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[221] *See Elsevier, Inc. v. Grossman*, 77 F. Supp. 3d 331, 346 (S.D.N.Y. 2015).

[222] *Golden Archer Invs., LLC v. Skynet Fin. Sys.*, No. 11 Civ. 3673 (RJS), 2012 WL 123989, at *3 (S.D.N.Y. Jan. 3, 2012); *see also Jonas v. Estate of Leven*, 116 F. Supp. 3d 314, 323 (S.D.N.Y. 2015) ("In deciding a motion to dismiss . . . for want of personal jurisdiction, the district court may consider materials outside the pleadings, including affidavits and other written materials."). *Highmore Fin. Co. I LLC v. Greig Cos.*, No. 21 Civ. 11021 (AT), 2023 WL 4865722, at *3 (S.D.N.Y. July 31, 2023).

[223] *Licci ex rel. Licci v. Lebanese Canadian Bank, SAL*, 732 F.3d 161, 167 (2d Cir. 2013) ("*Licci II*"). *Shaver v. Medicom Worldwide, Inc.*, No. 18-cv-5700 (DLC), 2018 WL 6200042, at *2 (S.D.N.Y. Nov. 28, 2018).

[224] *BWP Media*, 69 F. Supp. 3d at 349 (quotation marks and citations omitted).

long arm jurisdiction statute § 302(a)(1), the court has specific jurisdiction for causes of action arising from "transact[ing] any business within the state or contracts anywhere to supply goods or services in the state."[225] To satisfy section 302(a)(1), "(1) [t]he defendant must have transacted business within the state; and (2) the claim asserted must arise from that business activity."[226] A defendant transacted business where he "purposefully avail[s]" himself of "the privilege of conducting activities within New York."[227] "[P]roof of one transaction in New York is sufficient to invoke jurisdiction."[228] If an "individual act will not suffice," then an "ongoing course of conduct or relationship in the state" may satisfy the transacting business requirement.[229] When assessing contacts under § 302(a)(1), courts look at the "totality of Defendants' contacts with the forum state."[230] For the arise-from element, the plaintiff must show that there is an "articulable nexus" or "substantial relationship" between the "business transacted and the claim asserted," but the "inquiry under the statute is relatively permissive."[231]

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[225] CPLR § 302(a)(1), (a)(4).

[226] *Licci ex rel. Licci v. Lebanese Canadian Bank, SAL*, 673 F.3d 50, 57 (2d Cir. 2012), *certified question accepted sub nom. Licci v. Lebanese Canadian Bank*, 18 N.Y.3d 952, 967 N.E.2d 697 (2012*), and certified question answered sub nom. Licci v. Lebanese Canadian Bank*, 20 N.Y.3d 327, 984 N.E.2d 893 (2012) (quoting *Sole Resort, S.A. de C.V. v. Allure Resorts Mgmt., LLC*, 450 F.3d 100, 103 (2d Cir. 2006)).

[227] *Licci ex rel. Licci*, 673 F.3d at 61; *Chloe v. Queen Bee of Beverly Hills, LLC*, 616 F.3d 158, 169 (2d Cir. 2010) (defendant "need not be physically present in New York to transact business there within the meaning . . . of section 302(a)(1)… as long as he engages in '[p]urposeful activities' or 'volitional acts' through which he 'avails [him]self of the privilege of conducting activities within the ... State, thus invoking the benefits and protections of its laws…'").

[228] *Grossman*, 77 F. Supp. 3d at 344–345 (plaintiff put forth a prima facie case for personal jurisdiction over an individual defendant because "at least one" fraudulently purchased subscription was "mailed to New York."); *Deutsche Bank Sec., Inc. v. Montana Bd. of Invs.*, 7 N.Y.3d 65, 71, 850 N.E.2d 1140, 1142 (2006) (holding negotiating and buying bonds in New York state was sufficient for the court to exercise jurisdiction); *Chloe*, 616 F.3d at 162 ("Ubaldelli's single act of shipping an item into New York combined with the substantial business activity of Queen Bee, the entity with which Ubaldelli was affiliated, involving New York, give rise to personal jurisdiction over Ubaldelli.").

[229] *Licci ex rel. Licci*, 673 F.3d at 61, (citing *Fischbarg*, 9 N.Y.3d at 382–83, 849 N.Y.S.2d at 507, 880 N.E.2d 22 at 28 (defendants' "substantial ongoing professional commitment" supported long-arm jurisdiction)).

[230] *Chloe*, 616 F.3d at 164; *See also Licci ex rel. Licci*, 673 F.3d at 62 ("A court must have regard for the "totality of the circumstances.").

[231] *Licci v. Lebanese Canadian Bank*, 20 N.Y.3d 327, 339, 984 N.E.2d 893, 900 (2012) (citation omitted) ("We have consistently held that causation is not required, and that the inquiry under the statute is relatively permissive…"); *see also Sole Resort, S.A. de C.V. v. Allure Resorts Mgmt., LLC*, 450 F.3d 100, 103 (2d Cir. 2006).

Second, due process considerations require that the defendant have certain "minimum contacts" with the forum state so that the suit does not "offend traditional notions of fair play and substantial justice."[232] Where the plaintiffs assert specific jurisdiction, jurisdiction is based on "the affiliation between the forum and the underlying controversy."[233] The Second Circuit has observed it would be a "rare" case where § 302(a)(1) was satisfied by a defendant's transaction of business but the assertion of specific jurisdiction arising from the transaction nonetheless violated due process.[234]

The purchasers request that Zeldis's motion be held in abeyance pending targeted jurisdictional discovery. Zeldis seeks dismissal of all claims for lack of personal jurisdiction.[235] But in his declaration, Zeldis describes connections to New York, including: from 1995 to 2003, teaching at Cornell; and, in 2008, purchasing the first of three multi-million dollar apartments in New York, one of which he continues to own. These facts suggest Zeldis had continuous systematic contact with New York.[236] Given that lengthy contact, and the proximity of New York City to Princeton, N.J., it is more likely that Zeldis, a senior executive and Chief Medical Officer for Celgene, performed work on Celgene's behalf while in New York—such as fielding phone calls, attending meetings, and potentially overseeing clinical trials—than to suggest that this never occurred.

The purchasers request that, before the Court rules, they be permitted to take expedited, targeted jurisdictional discovery of Zeldis. The Court has considerable latitude in devising procedures to look at facts related to jurisdiction; and has discretion to order discovery if the

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[232] *Licci II*, 732 F.3d at 169–170 (citation omitted).

[233] *Id.* at 170 (citation omitted).

[234] *See id. Shaver*, 2018 WL 6200042, at *3.

[235] Zeldis Mem. at 3.

[236] *See* Zeldis Decl. in Supp. of Mot. to Dismiss, ¶¶11–17.

plaintiff has "made a threshold showing of jurisdiction and plaintiff's position is not frivolous."[237] Courts allow jurisdictional discovery when a plaintiff shows a "sufficient start toward establishing personal jurisdiction," which is less than a "prima facie showing of jurisdiction."[238] The "sufficient start" requirement is satisfied where the plaintiff identifies a "genuine issue of jurisdictional fact."[239]

V. CONCLUSION

The purchasers request that BMS and Insogna's motions to dismiss be denied; and that Zeldis' motion to dismiss be held in abeyance pending limited, expedited jurisdictional discovery.

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Respectfully Submitted,

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[237] *Wilson & Wilson Holdings LLC v. DTH, LLC*, 673 F. Supp. 3d 409, 414 (S.D.N.Y. 2023); *See also Unique Indus. Inc. v. Sui & Sons Int'l Trading Corp.*, No. 05-CV-02744 (KMK), 2007 WL 3378256, at *6–7 (S.D.N.Y. Nov. 9, 2007); *Phoenix Consulting Inc. v. Republic of Angola*, 216 F.3d 36, 40 (D.C. Cir. 2000) (courts should "give the plaintiff 'ample opportunity to secure and present evidence relevant to the existence of jurisdiction.'") (*quoting Prakash v. Am. Univ.*, 234 U.S. App. D.C. 75, 727 F.2d 1174, 1179-80 (D.C. Cir. 1984)).

[238] *DTH, LLC*, 673 F. Supp. 3d at 413 *citing, City of Alamaty v. Abhyazov*, 278 F. Supp. 3d 776 at 809 (S.D.N.Y. 2017) (*quoting Prakash v. Am. Univ.*, 234 U.S. App. D.C. 75, 727 F.2d 1174, 1179-80 (D.C. Cir. 1984)).

[239] *Id.* at 413, *citing, Daventree Ltd. v. Republic of Azerbaijan*, 349 F. Supp. 2d 736, 761 (S.D.N.Y. 2004) (*citing In re Magnetic Audiotape Antitrust Litig.*, 334 F.3d 204, 207-08 (2d Cir. 2003)); *see also Ehrenfeld v. Mahfouz*, 489 F.3d 542, 550 n.6 (2d Cir. 2007) (stating that it would be "legal error" for district court to "forbid[ ] jurisdictional discovery any time a plaintiff does not make a prima facie showing of jurisdiction").

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CERTIFICATE OF SERVICE

I, Whitney E. Street, certify that, on this date, the foregoing document was filed electronically via the Court's CM/ECF system, which will send notice of the filing to all counsel of record, and parties may access the filing through the Court's system.

Dated: April 18, 2024

/s/ Whitney E. Street
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